EXHIBIT M

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION
ATLANTIC COUNTY
CASE NO. 291 CT
MASTER CASE NO. L-6341-10

- - -

IN RE:
PELVIC MESH/GYNECARE
LITIGATION

- - -

CONFIDENTIAL - ATTORNEYS' EYES ONLY
VOLUME II
Friday, November 16, 2012

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Continued oral deposition of DANIEL STEVEN ELLIOTT, M.D., held at MAZIE SLATER KATZ & FREEMAN, L.L.C., 103 Eisenhower Parkway, Roseland, New Jersey, commencing at approximately 8:25 a.m., before Rosemary Locklear, a Registered Professional Reporter, Certified Realtime Reporter, Certified Court Reporter (NJ License No. 30XI00171000), and Notary Public.

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DANIEL STEVEN ELLIOTT, M.D., having been previously duly sworn, was examined and testified as follows:

EXAMINATION (Continued)

BY MR. SNELL:

Q. Good morning, Doctor. How are you doing this morning?

A. Fine.

Q. We're going to resume your deposition.

Between the end of the deposition yesterday and this morning did you review any materials, any literature, anything like that?

A. Just my private notes.

Q. I'm sorry. Your what?

A. My notes.

Q. What notes are these?

A. Just notes that I've taken on the depositions.

Q. Of the different Ethicon witnesses?

A. Correct.

Q. Any notes that you've taken on any other witnesses?

A. No. Just Ethicon depositions.

Q. So no notes on depositions in the Gross case; correct?

A. No. No. I can tell you Gauld or Gauld, Walji, Robinson, Kirkemo, Hinoul. I'll never get that one.

MR. ANDERSON: You did great on that.

THE WITNESS: There may be another one in there. Those are the ones I've --

BY MR. SNELL:

Q. Do you know Larry Sirls, a urologist?

A. I do not believe I've ever met him. He is in our same north central section of the AUA, which incorporates Michigan, so I believe he's in Michigan. So I may have encountered him at a meeting but, again, I don't recall ever meeting him.

Q. Have you ever seen him speak or present, that you recall?

A. I do not recall. I may have, actually. I don't recall.

Q. Do you have any criticisms of him

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as a surgeon?
A. No. I don't know him as a surgeon at all so I -- but I have no criticism.
Q. Do you know Elizabeth Kavaler, also a urologist?
A. No. To the best of my knowledge, I've never met her.
Q. Do you know Miles Murphy, urogynecologist?
A. No.
Q. Never met him or seen him?
A. To the best of my knowledge, no.
Q. Any criticisms of Miles Murphy that you have?
A. Well, I mean, ethically, no, surgically, no. I don't agree with some of the conclusions he reached in his papers, but that's limited to that.
Q. Vince Lucente, have you ever met him?
A. No.
Q. Have you ever seen him speak or present at any conferences?
A. Not that I know of. But we

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attend meetings that are going to be overlapped. I may have encountered him, but I don't recall ever doing that.
Q. That's what I was going to ask you.
Do you attend the AUGS conferences in addition to the urologic conferences that you -- strike that. That was a bad question.
Do you attend the AUGS conferences?
A. No. I attend primarily urologic meetings. However, with that said, the IUGA meetings I've attended at times, especially when they're in concert with the International Continence Society, which I'm much more involved in.
Q. What type of urologic conferences do you attend regularly, let's say in the past, since 2001 since you've been back at Mayo following your fellowship?
A. Regularly, the north central section of the AUA, which is the American Urologic Association. Then the AUA meeting, our national meeting. International

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Continence Society. I'd have to look at my -- because I attend meetings all over. There's a number of robotic ones.
Q. Okay.
A. In my CV it has the ones that were given presentations.
Q. Do you have any criticisms of Dr. Vince Lucente?
A. Again, the same as with Dr. Murphy: I don't have any surgical, ethical. My conclusions are different than his, but that's on an academic level.
Q. What conclusions do you have at an academic level that are different than Dr. Lucente's?
A. On the very broad thing -- broad scale, he is pro-mesh, I am anti-mesh in the case of pelvic organ prolapse done transvaginally.
Q. So you're pro-mesh for stress urinary incontinence; correct?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: I use meshes for stress urinary incontinence. In my own

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personal experience, I have not encountered significant problems with it, so relative to specifically my personal experience, it would be fair to say I'm pro-mesh.
BY MR. SNELL:
Q. And you're pro-mesh for the use of mesh to treat pelvic organ prolapse as long as it's not transvaginally placed.
A. Correct.
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: Correct. From transabdominal, laparoscopic or robotic, I am pro-mesh for that.
BY MR. SNELL:
Q. Yesterday we were talking about doing a concomitant hysterectomy with sacrocolpopexy.
A. Yes.
Q. Do you recall, in general, that?
A. Yes.
Q. We were talking about the risk of infection. Do you recall that?
A. Yes.
Q. When a hysterectomy is done at

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the same time as a sacrocolpopexy, the peritoneal cavity is exposed to the same bacterial -- strike that.

When a hysterectomy is done at the same time as a sacrocolpopexy, the peritoneal cavity is exposed to the same type of vaginal flora.

A. Flora, yes.

Q. And you're aware that clinical studies continue to be done in sacrocolpopexy cohorts that include patients who have a hysterectomy at the same time; correct?

A. I'm not aware of any ongoing studies. That's not to say they're not ongoing, I'm just not aware of any.

Q. In the past couple years you've seen studies where a certain percentage of the sacrocolpopexy patients did have a concomitant hysterectomy at the same time; correct?

A. Yes.

Q. Has the American Urologic Association come out with any type of statement that says that a hysterectomy

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should not be done at the same time as a sacrocolpopexy?

A. I'm not aware of any.

Q. Do you know if the American College of Gynecology has come out with a statement that says that hysterectomy should not be done at the same time as a sacrocolpopexy?

A. Again, I'm not aware of any.

Q. We talked yesterday about some of the different surgical procedures that you've performed for prolapse, such as colporrhaphy, sacrospinous ligament fixation, sacrocolpopexy, McCall's culdoplasty and the Mayo culdoplasty.

A. Culdoplasty, yes.

Q. And colporrhaphy was the first surgery that you were trained on for pelvic organ prolapse?

A. Yes. The anterior and posterior colporrhaphy.

Q. And that was in the early 1990s or mid-1990s?

A. Mid-1990s. 1997, probably, to be specific. That's when I had my first female

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urology rotation.

Q. And you know colporrhaphies had been performed for decades before that by surgeons in the field; correct?

A. Yes.

Q. And when you began performing colporrhaphies in 1997, there were no randomized, controlled trials with that type of procedure; correct?

A. Well, I can't recall what -- what the data was for 1997, but in 1997 the anterior colporrhaphy, there were not anything to randomize it to. There were tissue repairs.

I am not aware of any meshes used at that point in time transvaginally for anterior colporrhaphies. So, again, to have a randomized, controlled study, you have to have something to randomize it to.

Q. Correct. So there were no randomized, controlled trials for colporrhaphy versus sacrospinous ligament fixation; correct?

A. Those were going after different problems. Sacrocolpopexy is designed to

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treat apical prolapse. Anterior colporrhaphy is designed to treat anterior prolapse.

Q. So the answer to the question is, no, there were no randomized, controlled trials in colporrhaphy when I started doing them in 1997; correct?

A. Yes.

Q. And for the sacrospinous ligament fixation surgery that you were trained on were there any randomized, controlled trials in that procedure before 1990, that you're aware of?

A. I would have to review the literature. I am not aware.

Q. As you sit here today, you cannot identify any randomized, controlled trials with sacrocolpopexy before 1990; correct?

A. I'd have to -- to answer your question very specifically, as I sit here right now, no, I would be unable to come up with any; however, give me 15 minutes on PubMed, I'd come up with a large number.

Q. When we take a break, I'll give you 15 minutes to look on PubMed, and I want

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you to identify all of the randomized, controlled trials before 1990 with sacrospinous ligament fixation that you are able to come up with.
A. So --
MR. ANDERSON: Objection.
You said sacrocolpopexy before.
MR. SNELL: No. I --
THE WITNESS: You said sacrocolpopexy and the sacrospinous. Because you're going to have to be very specific what we're going to be comparing. And I'll need to have a computer that can access to and print off the manuscripts.
MR. SNELL: Give me one second. I thought my question was sacrospinous.
Okay. I see what you're saying.
BY MR. SNELL:
Q. The McCall's culdoplasty that you were performing during your training, had that been studied in a randomized, controlled trial?
A. I'm not aware of any on the top of my head, no.

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Q. The Mayo McCall culdoplasty, had that been studied in any randomized, controlled trials before you began doing it?
A. What would be the random -- what would be the control group in that?
Q. I'm not the doctor. I'm asking you, were there any randomized, controlled trials with the Mayo McCall's culdoplasty?
A. Well, I have to know what it's randomized to. It's a very vague question for me. Randomized to people driving a car, heart surgery, or what?
Q. No. Of course, randomized to other prolapse surgeries, Doctor.
A. Well, which one is the --
Q. I'm not talking about randomizing to people driving cars and things like that.
A. Yeah. That was an example. I need to know, randomized to which one? Because, again, there's going to be multiple different possible ones to be randomized to.
Q. What are the ones that Mayo McCall's culdoplasty could be randomized to?
A. It could be to sacrospinous fixation, it could be to McCall's

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culdoplasty, it could be to sacrocolpopexy.
Q. When you began performing the Mayo McCall's culdoplasty, were you aware of any randomized, controlled trials that studied it compared to the McCall's culdoplasty?
A. I am not -- sitting here right now, no, I'm not aware of any.
Q. When you began performing the Mayo McCall's culdoplasty, were there any randomized, controlled trials comparing it to sacrospinous ligament fixation?
A. As I'm sitting here right now, no, I cannot recall that.
Q. When you began performing the Mayo McCall's culdoplasty, were there any randomized, controlled trials comparing it to sacrocolpopexy?
A. As I'm sitting here right now, I can't recall it.
Q. Is it correct that during your fellowship training, you observed the sacrospinous ligament fixation being performed?
A. That is correct.

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Q. Now, did you testify yesterday that your instructors did not let you actually perform the sacrospinous ligament fixation during your fellowship?
A. There were two instructors that I worked with most significantly, two GYNs, the chair GYN at Baylor and then the other one was Dr. Cone, who was also on staff at Baylor.
The chair of the department at Baylor, he performed the procedure completely, palpation. It is his estimate that we did so few that it would be difficult to become proficient in it. Dr. Cone never performed a sacrospinous fixation. That's who I learned sacrocolpopexy from.
Q. So the chair at your fellowship did not allow you to perform the sacrospinous ligament fixation surgery during the fellowship; correct?
A. He didn't -- I assisted him. So he was the one who actually put the needles through.
Q. How did you assist him during the

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sacrospinous ligament fixation?
A. As far as initial dissection, retraction, holding sutures, closure.
Q. And this was in 1999 to 2000?
A. July of '99 to June of 2000.
Q. Are you aware that other fellowship programs in either the type of curriculum you were in for urologists or urogynecology had fellows who actually passed the suture through the sacrospinous ligament -- through the sacrospinous ligament during that procedure?
MR. ANDERSON: Objection as to time period.
THE WITNESS: Yeah. I cannot -- I cannot, you know, comment on what happened in other programs but I fully suspect they did. I have no reason to doubt they wouldn't.
BY MR. SNELL:
Q. During the sacrospinous ligament fixation, when you did the dissection, how did you do that?
A. It is the vaginal dissection through a midline vaginal incision,

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elevating the vaginal mucosa off the underlying tissues, and then Dr. Law -- actually, I believe it was Dr. Law was the chairman but that I could be wrong on --
Q. Okay.
A. -- would then take over and do the remainder of the dissection.
Q. And the retraction, how did you do that?
A. That is just with -- I mean, I can't recall the procedure exactly, but it would be -- you have some form of either malleable retractor, hand-held retractor of some sort exposing the underlying tissue as best you can, which is somewhat difficult.
Q. So it can be somewhat difficult to expose the underlying tissue during the retraction of a sacrospinous ligament fixation?
A. It can be difficult to set it up appropriately, but with the correct instruments it can be done.
Q. And what type of instruments are these that you would use during the sacrospinous ligament fixation retraction?

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A. Again, I can't recall.
MR. ANDERSON: Objection. Asked and answered.
Go ahead.
THE WITNESS: I can't recall that exact surgery, what we used. Most likely, it would be something called a narrow Deaver -- D-E-V-O-R, I believe -- or there's a renal retractor which is a similar thing. It's long, narrow and deep.
Again, there's the -- the various different malleable retractors, which are variable sizes, and you can adjust them to custom fit them to your -- whatever you need and the patient's anatomy.
BY MR. SNELL:
Q. So a malleable retractor is a type of retractor, it's not an attribute of the retractor.
A. No. It is -- it is a -- the answer to your question is yes to both your questions.
Q. Okay.
A. Malleable retractor is a piece of metal, a flat piece of metal, that is long,

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that can be any size, though for vaginal surgeries they tend to be long, they tend to be narrow. By narrow I mean 2 to 3 centimeters in width. And they can be 18 inches long. And then you can bend it anywhere, hence, the name malleable so, then again, you can get a custom fit to your surgery. Unlike a Deaver or a renal, which is a set size and you cannot adjust it, malleables are sizes of all ranges.
Q. And when you did the dissection for the sacrospinous ligament fixation, what surgical tools did you use for that?
A. Hydrodissection with a needle, a hypodermic needle filled with normal saline, a scalpel to dissect through to make your incision to gain access, then you'd use Metzenbaum's scissors to actually do the elevation along with Allis clamps, spelled A-L-L-I-S. And then you'd use the various different retractors. And that's probably a fairly comprehensive list of tools.
Q. Do all prolapse surgeries use surgical tools?
A. Well, I can't comment on all

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surgeries. They --
Q. All surgeries -- let me -- do all surgeries that you have performed, such as colporrhaphy, sacrospinous ligament fixation, sacrocolpopexy, do they all use surgical tools?
A. Yes.
Q. And the laparoscopic and robotic sacrocolpopexies that you've performed also use trocars?
A. Correct.
Q. And trocars are also used during stress urinary incontinence surgeries?
A. Technically speaking, yes. But trocar is a generic term. It just means -- it's a French word meaning three sides. And so, again, the trocars are vastly different in shape, function, but they are technically trocars.
Q. You mentioned that you were trained on hydrodissection during your fellowship in connection with sacrospinous ligament fixation; correct?
A. Specific -- I was trained prior to that in residency. I wouldn't say they

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trained me in fellowship. We used it in fellowship. I already knew how to do it.
Q. When were you trained to do hydrodissection?
A. It would have been 1997 when I did my female urology rotation.
Q. During your residency?
A. Correct.
Q. When was the Mayo McCall's culdoplasty first performed?
A. I would have to do a literature search on that. I believe it was Dr. Lee at Mayo who did it. His career spanned the '60s into mid-2000-something. I don't know exactly. Somewhere in there.
Q. Can you give me your best approximation?
A. If I were to guess, it would be in the '60s and '70s.
Q. Now, the McCall's culdoplasty was a procedure that was before the Mayo McCall's culdoplasty; correct?
A. I don't know. I would suspect it was because the Mayo culdoplasty is somewhat of a variation of the McCall's, and so I

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don't know the exact chronology of those.
Q. That's what I thought your testimony was yesterday, that the Mayo McCall's culdoplasty is similar to the original McCall's culdoplasty but it has some different anchoring technique or location.
A. Subtle, mild differences.
Again, I don't know which came first, if it was the McCall's variation of Mayo or Mayo is the variation of McCall's. So I don't know.
Q. The mesh that you use in your sacrocolpopexies that is made of polypropylene, does it come in a precut shape?
A. Yes. As you -- yeah, as you saw in the manuscript, it comes in a Y-shape.
Q. The da Vinci robot that you use to perform your robotic laparoscopic sacrocolpopexies -- strike that.
Does the da Vinci robot that you use to perform your robotic laparoscopic sacrocolpopexies have surgical tools that help aid in the surgery?

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A. Yes.
Q. Does the da Vinci robot have tools that allow dissection?
A. Yes.
Q. Does the da Vinci robot have tools that allow parts of the body to be grafts by the robot?
A. Yes.
Q. Does the da Vinci robot have tools which allow surgeons to tie knots during the procedure?
A. Yes.
Q. Do you use the patient brochures that da Vinci puts out for its robotic laparoscopic sacrocolpopexy?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: I don't believe they have any brochures on the sacrocolpopexy.
BY MR. SNELL:
Q. Do you use any patient brochures that da Vinci puts out?
A. No.
Q. In your general expert report you

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note that the traditional non-mesh POP repairs have failure rates up to 30 to 40 percent; correct?
A. I note that -- well, I have to see what page you're on.
Q. Page 14 is one of the places where you say that.
A. Okay. Yes. You have to read in the totality of that sentence. The misconceived notion that traditional repairs have failure rates up to 30 to 40 percent.
Q. The traditional non-mesh POP repairs had failure rates up to 30 to 40 percent when they were originally published; correct?
A. Well --
MR. ANDERSON: Objection.
THE WITNESS: -- I mean, I'd have to say that I put a lot of thought into what I said here and you're deleting "the misconceived notion."
MR. SNELL: No. No. I understand what your position is, Doctor.
THE WITNESS: Okay.
BY MR. SNELL:

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Q. But what I'm saying is, at the time these data were published on traditional non-mesh POP repairs, the failure rates were 30 to 40 percent, as reported back then; correct?
A. Correct. As you've stated there, yes, in the literature failure rates were reported up to 30 to 40 percent.
Q. In fact, Doctor, in the literature failure rates were reported at over 50 percent; correct?
A. I'd have to look at that. I don't know what reference you're talking about. If you show it to me, I could review that.
Q. Turn to Page 23, Doctor.
A. Okay. I'm there.
Q. Now, Figure 2 you have the different shapes of the Prolift® meshes; correct?
A. Correct.
Q. Total, anterior and posterior; correct?
A. Yes.
Q. From where did you obtain this

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Figure 2?
A. As I recall -- because, again, I've gone through so many documents -- as I recall, I got this off the Internet.
Q. Now, the shapes -- let me back up.
The Prolift® meshes are polypropylene meshes; correct?
A. Correct.
Q. And the shapes of the Prolift® meshes depicted in Figure 2 of your report at Page 23, those shapes were assessed by surgeons; correct?
A. I have no idea who assessed them.
Q. Isn't it your understanding, Doctor, that the French TVM surgeons assessed and determined these particular shapes for the Prolift® mesh?
A. My understanding is the TVM surgeons had a large piece of Gynemesh® and they cut them. I have seen in their documents -- excuse me -- their manuscripts shapes.
I don't know who was all involved in the design of this product, I

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mean, as far as the -- how the shapes got involved.
Q. Okay. I'm not sure if I asked you this yesterday: When was the last time you did a transobturator-placed sling?
A. Last week. Yeah, it would have been last week sometime, I believe. I do a large number and so I believe I did one last week. If not, then it was the week before that.
Q. And when you perform a transobturator sling placement, is it correct that you go in through the transobturator space?
A. I go through the obturator foramen.
Q. And you use trocars during that procedure?
A. Yes.
Q. Is the obturator foramen the same area where the anterior Prolift® mesh trocars pass?
A. They both go through the obturator foramen.
Q. When you do your obturator

foramen passage during a transobturator sling, is that a blind passage?
A. Yes.
Q. At the top of Page 30 of your report, Doctor --
A. Okay. Page 30.
Q. -- here you're talking about the surgical technique with Prolift® and in particular you are discussing the dissection of the vaginal tissue off of the bladder and surrounding tissues must be carefully performed so as to avoid injury.
Do you see where I'm at?
A. I see on 29 start talking about hydrodissection, incisions made. Oh, here you go. Yes, starting on the bottom of 29. The dissection of the -- yes, I see that.
Q. So we're at the same place?
A. Yes. Top of Page 30.
Q. So you're talking about the dissection of the vaginal tissue off of the bladder and surrounding tissues must be carefully performed so as to avoid injury; correct?
A. Yes.

Q. You would agree that dissections for any pelvic organ prolapse surgery must be carefully performed; correct?
A. Correct.
Q. During the sacrocolpopexy procedures that you perform, Doctor, do you ever trim or make any alterations at all to the Y-shape mesh?
A. Yes.
MR. ANDERSON: Objection. Asked and answered.
Go ahead.
THE WITNESS: Yes.
BY MR. SNELL:
Q. Under what circumstances would you do that?
MR. ANDERSON: Same objection.
Go ahead.
THE WITNESS: The mesh as it comes in the box is quite large. The anterior and posterior limbs are quite long and so is the tail, so you have to trim it to customize it to the patient's size.
BY MR. SNELL:
Q. Do you also at times have to trim

the mesh you use during the sacrocolpopexy because of findings you encounter once you enter the abdomen and see the surgical field in which you're working, such as scarring or any other medical condition you may encounter, Doctor?
A. No. The only thing -- the only reason we trim it is because preoperatively, we don't know the full extent of the vaginal length and its relationship to the sacrum.
So that's why when it comes in the box, the actual device is quite long, so we always have to trim it to shorten the limbs and the tail. But it would be no bearing upon what we find inside the patient's body, it's just the vaginal length relative to the sacrum.
Q. Is it correct that you perform standard mesh attachment to the -- strike that.
Is it correct that you attach one part of the polypropylene mesh that you use in sacrocolpopexy to the sacrum?
A. Correct.
Q. Do you always attach that

polypropylene mesh to the sacrum in the same location?
A. We are -- the exact same, no, but we are very, very close. We're looking to the S-2, 3, 4 region, the promontory. We may vary half centimeter or more between patients.
Q. You would agree that with any pelvic organ prolapse surgery, even in the hands of the most highly skilled surgeon, there can be significant complications; correct?
A. Yes.
Q. Turn, if you would, to Page 38 of your report, Doctor.
A. Okay.
Q. And I'm on the paragraph that begins, "Also, very interesting data has emerged."
Are you with me?
A. Yes, I see it.
Q. Tell me what studies or data you are referring to when you say, "Also, very interesting data has emerged this" -- it should be "that"; right?

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A. This shows -- yeah, that. Yeah. Grammatical error, yeah.
Q. What studies or data are you referring to and relying upon for the statement, also, comma, very interesting data has emerged that shows that women following POP procedures that have perfect vaginal support actually have a lower QOL and subjective improvement compared with women with lesser degrees of support?
A. Well, if we continue down, we have that reference at the bottom which is referencing internal documentation, depositions I've read, these manuscripts that are referenced, specifically that the vagina and the pelvis is dynamic, and that's what is evolving the thought process, that fixed is not good, movement is good.
A vagina, the pelvic floor needs to be more like, for lack of a better phrase, like a trampoline as opposed to like plywood. There has to be give to it to accommodate movement.
Q. For the statement that they actually have a lower quality of life and

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subjective improvement compared with women of -- with lesser degrees of support, is there a clinical study in humans that demonstrates that, lower quality of life and subjective improvement?
A. The one that I can think of off the top of my head was Jacquetin. That's the French gentleman, who, again, I believe he is in the TVM study, a lecture I read of his in the IUGA meeting in Lake Como, Italy, 2009, talking about the dynamic nature and fixed and contraction results in pelvic pain where he had a 19.6, he referred to it as painful contraction or painful pelvis -- painful fixation. I'd have to look at the exact study, how he phrased it.
Q. Was this based upon quality-of-life scale scores?
A. I did not see that referenced in his -- in his presentation.
Q. Okay. Turn to Page 41.
Are you critical of the use of POPQ scoring in prolapse studies?
A. No.
Q. Is there any other anatomic

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prolapse scoring classification system that you are aware of that has been endorsed and recognized by the International Continence Society?
A. Well, there's the Baden-Walker grading system, B-A-D-E-N-Walker.
Q. Was that system before or after the POPQ system was recognized by ICS in 1997, '98?
A. I --
MR. ANDERSON: Objection.
Go ahead.
MR. SNELL: Let me clean it up, then.
BY MR. SNELL:
Q. Was the Baden-Walker system before the POPQ system?
A. It pre-existed it, yes.
Q. Page 41, a little ways down in that paragraph, "At this same time Ethicon knew."
Do you see me there?
A. Yes.
Q. When you note that the French results showed an 18.4 percent failure rate

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at 12 months after surgery, you are referring to the POPQ scoring?
A. I am referring -- I'd have to look at the reference specifically, which we have down there, the Ethicon internal documents. I believe that we're referring to anatomic failure, so anatomic POPQ failure.
MR. ANDERSON: Next time you get to a breaking point.
MR. SNELL: Okay.
BY MR. SNELL:
Q. When you talk about the complication rates with Prolift®, you note that the true incidence is not known due to multiple factors.
A. Yes.
Q. Do you know if complications with colporrhaphies are routinely submitted to the MAUDE database?
A. Standard non-tissue repairs would not be because my understanding is the MAUDE database is medical device recording, and so since there's no implant or substance put in, it should not be reported.

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Q. In your report you discuss granulation tissue; correct?
A. Yes.
Q. Not all granulations lead to mesh exposure; correct?
A. Correct.
MR. SNELL: We can take a break.
(Recess, 9:20-10:13 a.m.)
MR. ANDERSON: Can I make my statement on the record now?
MR. SNELL: Oh, yes. Of course. Of course.
MR. ANDERSON: So counsel has referred a couple of times to the fact that Ethicon has, in fact, filed a Motion to exclude the supplemental report of Dr. Elliott, and that Motion is on file with the Court.
Two points that I would like to make on the record regarding that. One is that, as far as I understand it, part of the subject of that Motion would be that any opinions he has with regard to the Linda Gross case and the Pamela Wicker case were

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developed after his initial report was filed.
And with regard to that first point, I would just state that Dr. Elliott is here, he's -- for two days and he is prepared to answer any questions that counsel may have with regard to his review of the Pamela Wicker case and the Linda Gross case and that it's going to be virtually impossible, given his schedule at Mayo, to have him back for a deposition, to sit for a deposition to answer questions about those two prior to the trial as it is currently scheduled.
And so I would just ask that if counsel has any questions, even if later on that part of his deposition is stricken and his opinions in that regard are excluded, that that would be a better time to deal with that rather than waiting to see how the Court is going to rule and then being in a position where they don't have an opportunity to depose Dr. Elliott.
The second point that I would like to make with regard to the Motion is

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that the supplemental report by Dr. Elliott is not in its entirety related to just the Pamela Wicker case and the Linda Gross case, rather, there are materials that he has reviewed since the time of his initial report, like depositions of Ethicon employees, documents that were produced after we would have had an opportunity to have him look at them prior to his initial report, et cetera, that are also contained in the list of materials reviewed and he has stated in his report, in agreement with New Jersey law, that the additional materials that he has reviewed support his initial opinions as set forth in his initial expert report dated June 15, 2012.
MR. SNELL: As I've stated a couple of times during this deposition, we are seeking and have filed a Motion to exclude Dr. Elliott's, what is termed the November 7th, 2012, supplemental report. This report is, in fact, a brand-new series of case-specific reports.
Dr. Elliott testified yesterday that he had not reviewed any records,

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depositions, radiology, urologic testing or any case-specific materials particular to the Gross or Wicker cases before issuing his general report in June 2012. I will not reiterate all of the bases in the Motion. Counsel is on notice of it.
I will say, if I do choose to ask Dr. Elliott questions about his supplemental report from November 7, 2012, of which there is only a single paragraph about Mrs. Gross and a single paragraph about Mrs. Wicker and which falls well short of the New Jersey standard of setting forth opinions and bases for those opinions, I am not in any way waiving our Motion and our arguments.
Thank you.
And for the record, the supplemental report that plaintiff and myself are referring to has been marked to this -- in this deposition as Elliott Exhibit Number 2.
MR. ANDERSON: Okay.
BY MR. SNELL:
Q. Now, let's do some questioning.

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All right.
Doctor, can you tell me the medical areas in which you are Board-certified?
A. Urology.
Q. Are there any urology subspecialty Board certifications?
A. Pediatrics, and then it's going to be female urology, reconstructive surgery.
Q. And you're not Board-certified in female urology, reconstructive surgery?
A. No one is at this point.
Q. Is that a Board that's coming down the road?
A. June 21st is the exam. You had to submit application and your -- your clinical practice, surgical practice has to be reviewed and approved to be able to sit for the exam. So June 21st I'll be sitting for the exam.
Q. Did you pass your Board certification for urology on the first attempt?
A. Yes.

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Q. All parts of it?
A. Well, there are -- yeah. There are three components to it, when I took the exam, and I passed all three.
Q. I understand you're a Medical Doctor, but beyond your standard medical training, do you have any advanced training in pathology?
A. No.
Q. How about radiology?
A. No.
Q. What about psychiatry?
A. No.
Q. What about infectious disease?
A. No.
Q. You're not Boarded in infectious disease; correct?
A. Correct.
Q. I want to focus on the time period after your fellowship when you came back to the Mayo Clinic. Okay, Doctor?
A. Okay.
Q. Can you tell me, in general, how you spend your clinical week, work week?
A. It's every other day either in

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clinic or surgery, so 50 percent of my time is in one or the other, so it varies from week to week. One week will be Monday, Wednesday and Friday in the operating room with Tuesday, Thursday being clinic, the subsequent week will be just the reverse of that, Monday, Wednesday, Friday clinic and then Tuesday, Thursday OR.
Q. Do you do any teaching?
A. Yes.
Q. When do you do teaching?
A. When?
Q. Yes.
A. You mean what time of the day? What do you mean? Time of the year or --
Q. What time -- can you tell me -- do you teach medical students, residents, fellows at the Mayo Clinic?
A. Yes.
Q. Can you tell me about the teaching you do at the Mayo Clinic?
A. I teach medical students every year or every other year. That would be when I'm requested to speak about general urology issues, speak with the residents on

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a usually two to three times a year on voiding dysfunction-specific topics, which the fellows are involved with that.
I then also teach a recertification -- internal medicine recertification exam where every year two times a year a medicine resident -- excuse me -- medicine staff from around the nation come in and it's an update course, so I teach Board-certified internal medicine individuals.
Q. Do you have certain amounts of time you set aside for administrative responsibilities?
A. No. My responsibilities are only clinical, so I'm 100 percent clinical.
Q. Can you tell me what the risk factors are for prolapse?
A. It's a fairly comprehensive -- excuse me -- a very detailed list. You want to go through point by point or --
Q. Just tell me what they are and, if you can, can you tell me them in order of importance, if you have them in such an order?

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A. Okay. If it's relative of importance, it depends upon whose perspective, the patient's or mine, because those -- there have been studies showing that there's a difference of what a patient wants to gain out of surgery versus what the doctor expects to gain, those things.

So that's not to be difficult, I just kind of need to know if I'm talking to a patient in what they want to know versus giving a lecture to other surgeons and what to expect.

Q. Okay. I think we strayed off and lost communication. I was looking for the risk factors for prolapse, not --

A. Okay.

Q. -- the surgery itself. So can you tell me the risk factors?

A. Oh, risk factors for prolapse. I'm sorry. I misunderstood your question.

Q. It's okay, Doctor.

A. Risk factors for prolapse: previous surgery for prolapse; previous hysterectomy; obesity; questionably, menopause; questionably, age; indirectly,

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smoking; repetitive lifting; heavy lifting, that would be a lifestyle issue; genetic predisposition. Off the top of my head, that's it. I can't say that's a comprehensive list.

Q. Can you tell me the number of sacrospinous ligament fixation surgeries you have performed at Mayo Clinic?

A. Zero.

Q. The use of mesh in abdominal sacrocolpopexy was a use that was developed by physicians; correct?

A. I don't know who developed it. I would -- I would assume it was developed by surgeons doing the procedure themselves.

Q. I think we discussed this yesterday, but surgeons were using materials like autologous materials for sacrocolpopexy and they found less than satisfactory rates of recurrence, according to the medical literature; correct?

A. Correct.

Q. And then surgeons began looking towards synthetic meshes as an option to, hopefully, reduce that incidence of

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increased recurrence; correct?

A. Correct.

Q. What other procedures do you ordinarily do at the time of an abdominal sacrocolpopexy?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: Usually we'll be putting in an -- doing an anti-incontinence procedure at the same time.

BY MR. SNELL:

Q. Is that a sling procedure like we discussed earlier today?

A. Usually it would be a sling, yes.

Q. And what type of sling would that most commonly be?

A. Most commonly would be a suprapubic sling.

Q. A suprapubic sling made of polypropylene mesh; correct?

A. Correct. Correct.

Q. A suprapubic sling using polypropylene mesh placed transvaginally; correct?

A. Correct.

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Q. If you were going to counsel one of your patients on the potential risks of an abdominal sacrocolpopexy, what risk would you identify to your patient?

A. Risk of bleeding, risk of wound infection, risk of bowel abnormalities, specifically bowel obstruction from the surgery itself.

Again, as long as we're being very clear we're talking about abdominal sacrocolpopexy because the discussion is different for robotic sacrocolpopexy.

Q. Okay.

A. Bleeding -- I can't talk because she keeps doing it -- wound infection, and then erosion of the mesh.

And then the inherent ones as far as just anesthesia itself. That's cardiac event, thromboembolic event, which are not necessarily specific to the surgery, it's just undergoing anesthesia. And then recurrence also.

And then lastly, specifically, treating urinary incontinence when you're concurrently treating prolapse is tricky,

and so an individual may not have incontinence at the time of preoperatively, it's due to -- it's occult, and when you reduce the prolapse, you can uncover the incontinence. So that's why I'll do a prophylactic sling now in my practice. That has evolved. So I warn them very clearly about the possibility of developing stress urinary incontinence following surgery.

Q. For the robotic laparoscopic sacrocolpopexy what risks would you inform your patient of?

A. Most importantly, the 5 percent risk of converting to open, meaning we would not be able to accomplish the procedure using the robot. So they have to understand that there's a chance they could end up with an incision.

The risk of bladder injury at the time of the procedure would be slightly higher than doing it open so we focus more time on that.

The risk of bleeding is less in our series so I don't spend too much time on that. Risk of small bowel obstruction we

have not seen. It is highly unlikely because of the minimal manipulation of the bowel at the time of the procedure.

And then also then mesh extrusion again. That would be the same discussion as with the abdominal sacrocolpopexy.

And then the same as far as with the urinary incontinence. There's no difference there.

Q. Would you also have the same discussion with regard to the risk with the anesthesia?

A. Yes. Yes.

Q. Now, for the abdominal sacrocolpopexy you used the term "mesh erosion" and in the robotic you said "mesh extrusion," and I just want to understand, is there some difference in the discussion or was that just a difference of terms you happened to use in the last minute or two?

A. Yeah. That -- I misspoke. It's extrusion. And that is a problem with our nomenclature at this point in time. There's -- the words are too similar. It's very

confusing.

Q. If you were doing a colporrhaphy, what are the risks you would identify to your patient?

A. Okay. We'd have to break it up to either anterior or posterior because I would say the risks are going to be different between the two.

So if you want to start with anterior colporrhaphy, same risk as far as bleeding. I do -- we do not -- then incontinence following the procedure.

Almost always at the time of anterior colporrhaphy I am putting in a concurrent sling is my practice, again, because of the occult incontinence.

I briefly discuss wound infection; however, I just don't see that in my practice. Let's see. What else? Inadvertent bladder injury.

And then lastly, I inform them that I always do a cystoscopy because there's the possibility of inadvertently obstructing a ureter.

And then the other risks as far

as the -- just the anesthesia itself.

Q. Are you familiar with the CARE study that looked at abdominal sacrocolpopexy?

A. I vaguely remember -- I -- we don't walk around talking about the CARE study but I remember reading it or something. I know the authors involved with it.

Q. For colporrhaphy do you also tell your patients that they may develop de novo dyspareunia?

A. We discuss it. In my practice and in my experience, it's been exceedingly rare.

Q. You're aware in the literature that it's been, de novo dyspareunia has been reported in over 15 percent of patients in different studies for colporrhaphy?

A. Well, according to what I've read in the depositions, according to Ethicon, that's rare. Because they talk about extrusions being that rate and they called it rare.

MR. SNELL: Move to strike.

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BY MR. SNELL:
Q. I'm not asking you to characterize one thing versus another one as a concept. I'm just asking you, you're aware in the medical literature that there has been de novo dyspareunia seen in over 15 percent of patients in different studies involving colporrhaphy?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: You'd have to break it down to anterior versus posterior. Posterior does have a higher incidence of dyspareunia, anterior has less.
So the 15 percent number, I just want to make sure what study, if, again, it's anterior versus posterior. Because, no question -- see, we haven't gotten to posterior yet.
When I talk about posterior colporrhaphies, I do discuss dyspareunia in a lot more detail because it is definitely a larger risk with that procedure.
BY MR. SNELL:
Q. Sacrocolpopexy, do you discuss

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the potential risk of dyspareunia?
A. We spend some time on it. However, we also talk a lot with the sexual history preoperatively to know if there's -- if, number one, if they're sexually active.
If they're not sexually active and there's no anticipated future sexual activity, I do not spend much time with it.
If they are sexually active, then we usually state that it is -- tends to be improved following it because we restore more normal anatomy. I don't guarantee that but we -- we do it very -- each patient is going to be managed differently depending upon where they're coming in with their sexual history at that point in time.
Q. And you're aware that the medical literature reports rates of de novo dyspareunia in patients who have undergone sacrocolpopexy -- strike that.
You're aware that the medical literature reports rates of de novo dyspareunia exceeding 10 percent in patients who underwent sacrocolpopexy; correct?
MR. ANDERSON: Objection.

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Go ahead.
THE WITNESS: Well, number one, I'd like to actually see that study; however, that does sound appropriate.
BY MR. SNELL:
Q. Pelvic organ prolapse surgery is a fairly complex surgery; correct?
A. I would agree with that, that it takes learning to know how to do it. The surgical dissection, the knowledge of the anatomy, the consequences of surgery, I would agree with your statement.
Q. It's the type of surgery that's best performed in the hands of a specialist; correct?
A. Well, it depends what you're defining as specialist. It needs to be done by a urologist who's familiar with the pelvic anatomy and pelvic organ prolapse or a gynecologist or a urogynecologist who's familiar with it.
A specialist, I would not say a general surgeon should do it, but it is not somebody who necessarily needs to have a fellowship.

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Q. Do you know, how many urology fellowships were there in the United States like the one that you attended where you focused on female reconstructive prolapse surgeries, urinary incontinence surgeries, in 2005?
A. 2005. I won't be able to give you a number in 2005 because it is evolving because starting in 2008 or 2009 is when the GYN Board and the American Urologic Association -- or no, that's wrong. The Board of American Urology, ABU, American Board of Urology, when they combined to set up criteria for a female urology/urogynecology fellowship.
So in 2005 I don't know the number. Currently, there are I believe like 15, 16, my last check.
Q. Is that urology only or --
A. It's both.
Q. -- is that a combination of urology and urogynecology fellowships?
A. There is now no such thing as urology or gynecology. All fellowships that have been approved are combined.

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Q. In 1999 and 2000, when you did your fellowship, how many other similar fellowships were there for urologists, such as yourself?
A. Yeah. I don't know because it was in the stages where things were coming about so it was not an issue that it was discussed. I don't know. I would think, actually, there would be fewer back then.
Q. So you would agree it's a fairly small group of surgeons who are being trained in these fellowships currently; correct?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: Relative to the number of urologists and gynecologists being trained every year, it is correct to say that those going through fellowships either in, again, this combined fellowship, I tend to call it female urologists because I'm a urologist, but the combined fellowship percentage-wise, that would be a select group.
BY MR. SNELL:

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Q. When a patient comes to you for prolapse, your consultation and treatment are geared towards that specific patient; correct?
A. Correct.
Q. And that takes into account that specific patient's symptoms; correct?
A. Correct.
Q. And you would agree it's important to discuss the different possible alternative treatments with patients?
A. Absolutely.
Q. And you, obviously, counsel patients on different surgical options which you believe may be appropriate for a given case; correct?
A. Correct.
Q. Let me say that again.
As a surgeon, you, obviously, counsel patients on different surgical options which you believe may be appropriate for that particular patient; correct?
A. Correct.
Q. And as a surgeon, one of the issues that would be important for a surgeon

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to consider with respect to the procedures is those procedures with which he or she feels comfortable with; correct?
A. Not just comfortable with but also competent in performing.
Q. I'm going to get there.
You would agree that it's important for the surgeon when considering what surgical options to offer that he or she feel comfortable with the surgical options offered; correct?
A. Correct.
Q. And if the surgeon is not comfortable with doing a particular surgery that the patient needs, then it would be appropriate to refer the patient elsewhere; correct?
A. In my opinion, yes.
Q. And if a surgeon is not familiar with doing a particular surgery that the patient needs, it would be appropriate to refer the patient elsewhere as well.
A. Yes. Correct.
Q. And in offering potential surgical options, it's your opinion that the

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surgeon should be competent in those particular surgical options he or she offers; correct?
A. Yes. Yes, that is correct.
Q. And only that surgeon knows the surgeries with which he or she is competent to perform; correct?
A. No. I'd say probably also his OR staff would also know. You are correct, but there are other people who can -- on the inside who would know.
Q. We earlier talked about your credentialling.
How did you actually go about determining which surgeries you would seek credentialling for?
A. Well, based upon my fellowship and the surgical numbers that I compiled and the staff, the chair at Baylor then writes up a letter to send to the Mayo surgical committee saying, Dr. Elliott during his fellowship with me on such and such a date to such and such a date completed X number of surgeries, I have witnessed these surgeries and follow-up and feel he is above

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and beyond competence. Competence is the entry level. Okay?

And so then I go for the credentialling committee and I have to say, here's what I feel comfortable doing, the procedures, and then they credential it.

You have then, I can't recall exactly now, it's a one- or two-year time period that you are then observed by a colleague competent in those procedures to make sure you are performing those procedures to the highest level possible.

Q. So you only sought credentialling on those procedures in which you had been trained; correct?

A. No, not necessarily. It was yes, but it was also in management and treatment of pelvic organ prolapse. So it was not limiting me to the development of future techniques.

Q. You sought credentialling with respect to the procedures that you felt comfortable with? Is that a fair statement?

A. Yes, that is.

Q. Switch to a different topic.

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I believe you testified yesterday that you've never used or implanted Prolift®; correct?

A. Correct.

Q. Have you ever used or implanted Apogee®?

A. No.

Q. Have you ever used or implanted Perigee®?

A. No.

Q. You never underwent or participated in any of the professional education programs for Prolift®; correct?

A. Correct. I did not.

Q. You never did any cadaver training with respect to Prolift®; correct?

A. I did not.

Q. And you never underwent cadaver training with respect to the use of any mesh products for prolapse repair; correct?

A. No. I'm just trying to remember. In fellowship we may have had cadaver labs on the sacrocolpopexy because our staff was involved in AUA as far as the individual to come in for learning and I may have been

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involved in cadaver labs with the sacrocolpopexy, but not transvaginal.

Q. It's correct you never underwent any cadaver lab training with respect to transvaginal placement of mesh.

A. Correct.

Q. I take it you never talked with any of Ethicon's sales representatives about Prolift®?

A. I don't recall ever meeting with one. I run it so that I very rarely have any interaction with the industry. But when we go to meetings, they swarm around you. So I could have encountered one.

Q. As you sit here today, do you have any specific recollection of having conversations with an Ethicon sales rep regarding Prolift®?

A. None, no.

Q. Before being engaged in this litigation, you had never reviewed any of the marketing materials for Prolift®; correct?

A. That is correct.

Q. Before being engaged in this

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litigation, you had never observed a surgery involving Prolift®; correct?

A. Not to my recollection, no.

Q. Now, have you seen surgical videos of the Prolift® surgery?

A. Yes.

Q. The surgical videos that you saw on the Prolift® surgery were within the context of this litigation; correct?

A. Correct.

Q. They were surgical videos provided to you by the plaintiffs' lawyers; correct?

MR. ANDERSON: Me.

BY MR. SNELL:

Q. Mr. Anderson; correct?

A. Correct. Yes.

Q. Have you participated in any professional education programs for any manufacturer of pelvic mesh?

A. For pelvic mesh? So participated with pelvic mesh?

Q. Yeah.

A. No.

Q. Okay.

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A. For prolapse, no.
Q. Have you ever participated in any professional education programs for a manufacturer of mesh used to treat stress urinary incontinence?
A. Yes.
Q. And which manufacturers were those?
A. AMS and Coloplast.
Q. Now, obviously, you were never a Prolift® preceptor; correct?
A. Correct. I was not.
Q. And you were never a Prolift® proctor; correct?
A. No, I was not.
Q. Have you ever called and spoken to a Prolift® preceptor?
A. No.
Q. Have you ever called and spoken to a Prolift® proctor?
A. No. But I've had conversation -- when I have patients referred to me with complications, I have spoken to the outside physician who put the device in. I don't know if -- what their status was.

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Q. Before becoming engaged in this litigation, had you ever reviewed the Prolift® instructions for use?
A. No, I had not.
Q. Before becoming involved in this litigation, had you ever read the instructions for use for Gynemesh® PS?
A. No.
Q. Before becoming involved in this litigation, had you ever reviewed the IFU for any other mesh used in pelvic floor reconstruction?
A. Yes. The Coloplast product. And then I believe I was also provided one for the AMS product. That was quite a long time ago but, yes, they had provided that for me.
Q. And the Coloplast product was a sling product?
A. No. They're mesh.
Q. The AMS product was also a mesh?
A. A mesh, correct.
Q. Is that the IntePro that you referenced yesterday --
A. No. No.
Q. -- or something else?

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A. This was something else. It was the Apogee®, Perigee®, one of those two, or Elevate®. And then the Coloplast product, I don't even recall what their name was, but the reps were pushing it.
Q. Have you ever been requested by a manufacturer or a regulatory agency to consult on the contents of an instructions for use?
A. No.
Q. Have you ever been requested to advise on the content of a surgical technique manual?
A. For a manufacturer?
Q. By a manufacturer or some governmental agency.
A. No. No. I mean, I've given opinions for journals in their surgical descriptions section for various different surgeries I perform but not for an industry or a regulatory body.
Q. Before being engaged in this litigation had you ever seen a surgical technique manual published by a manufacturer?

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A. Yes.
Q. Which one?
A. Well, that would be AMS and Coloplast also.
Q. The same ones you earlier referred to.
A. Yes. And then also for their suprapubic sling and transobturator sling and their male incontinence procedure for Coloplast.
Q. Did you have any criticism of those surgical technique manuals?
A. What I'm looking at -- well, it depends on what procedure, if I'm coming in with little knowledge or a lot of knowledge.
If I have a lot of knowledge, I'm usually going to be quite critical because I'm going to see where I feel there are deficiencies or warnings.
If I am a novice to it, like when I first started doing transobturators, I didn't know enough to know where the pros and cons are.
Q. When you first started doing transobturator sling surgeries, you didn't

know enough to know what the pros and cons were of that procedure? Is that what you're saying?
A. What I'm saying is, when I started doing transobturator in, whenever that was, 2002 to 2004 -- and, again, I stated that I believe I was the first one to do it in the State of Minnesota -- no one had experience in it.
It was designed, invented and patented in France and so the U.S. introduction was, as I recall, through Mentor, because they had the patent on it. So no one had knowledge of it.
I understood vaginal dissections, I did not understand the transobturator route because no one had ever heard of it before. So that's why I say as far as novice. I had knowledge of anti-incontinence procedures but not the transobturator route.
Q. And as you gained experience with using the transobturator route, you became more and more comfortable with it?
A. Yes.

Q. And you still consider it an important option in your armamentarium today to treat women with stress urinary incontinence; correct?
A. For a select group of individuals, yes, it's a very important part of my practice.
Q. Prior to becoming involved in this litigation, you had never seen a patient brochure for Prolift®; correct?
A. Correct.
Q. Prior to becoming involved in this litigation, had you seen the patient brochure for any prolapse mesh product?
A. Yes. The Coloplast and the AMS product.
Q. Did you ever use those patient brochures?
A. No. No. It was the representative, it was the reps for Coloplast, it was the vice-president of AMS who gave me the brochures, and I never did do the procedure nor hand them out to any patients.
Q. Do you know if other surgeons at

Mayo Clinic were doing those procedures?
MR. ANDERSON: Those procedures?
MR. SNELL: The ones that you identified, the Coloplast and the AMS mesh procedures.
THE WITNESS: Well, no, those -- to the best of my knowledge, nobody at Mayo does any mesh for pelvic organ prolapse, for transvaginal route.
BY MR. SNELL:
Q. Do you ever use patient brochures -- strike that.
Before this, becoming involved in this litigation, did you ever use patient brochures for sling products?
A. I -- yes, I give the patient brochures for the transobturator sling by Coloplast, the suprapubic sling -- well, actually, they're both, they're encompassing both, suprapubic and transobturator, and they also give the brochures for the artificial urinary sphincter.
Q. And the patient brochures are designed to be used in consultation with the

surgeon, like yourself; correct?
A. Correct.
Q. Would you ever perform a surgery on a patient who came to you who said, Doctor, I've looked at a patient brochure and I want to have this particular type of surgery without actually counseling and examining the patient?
A. No.
Q. Do you know what patient brochures were available to patients in your clinic at Mayo -- strike that. Let me back up.
Would you actually give these patients the brochures for the urinary incontinence products?
A. Yeah. Either myself or my physician assistant would.
Q. Did you keep them in your office or were they out in the waiting area or some other place?
A. In my office. We are not allowed at Mayo to have any industry products out.
Q. Did you prepare any materials yourself for your patients for whom you

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would use mesh in to treat their prolapse?
A. No.
Q. In the course of your teaching, did you train any residents or fellows on how to treat mesh erosions or exposure that occur following a sacrocolpopexy?
A. In the past. But we haven't had one in six or seven years. So the current group of fellows have not -- residents have not seen it.
Q. Have you trained them on -- let me re-ask it.
Have you trained residents or fellows on how to treat mesh erosion or exposure should it occur following a sacrocolpopexy?
A. Yeah. I say if trained as in past tense, yes, I have.
Q. And if you had a mesh erosion or exposure with a sacrocolpopexy, how would you go about telling residents or fellows the step-wise progression of treating that complication following the sacrocolpopexy procedure?
MR. ANDERSON: Objection.

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Go ahead.
THE WITNESS: I would first counsel them that any patient that calls up who has had a mesh, whether it be sling or prolapse, to have a high index of suspicion if a patient calls up with a discharge. Okay. So, first of all, it's a warning. Always be thinking about that.
Then I would have them say that we cannot treat this over the telephone, meaning I can't just call in something. You always have to see the patient, talk to them, get a good history, get a kind of feel for what's going on and the severity of it, then do a very thorough pelvic exam. Possibly, if there's any urinary complaints, then do a cystoscopy, make sure there's no bladder perforation or erosion specifically.
Then on the pelvic exam specifically with a speculum and also just a bimanual because sometimes you can't see it but you can feel it so you have to do both, and you have to take your time because the small ones are easier to miss, the large ones are not.

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You also have to, when you do your exam be looking, is there a discharge, does it look erythema, erythematous, is there a specific amount of granulation tissue? Then once all those things are done, then you have to evaluate, again, like we talked about yesterday, the size of the infection, all those things.
BY MR. SNELL:
Q. And then the same would hold true then in the case of a sacrocolpopexy, as our discussion yesterday, you would attempt to treat it most conservatively first.
A. Dependent upon, yeah, the severity of the problem. But yes, you -- you start as conservative as possible for that given patient.
Q. So for a mesh exposure or erosion with sacrocolpopexy, you would still try to treat it as conservative as possible for a given patient.
A. Correct.
Q. And based upon the patient's unique presentation and your findings on exam.

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A. Correct.
Q. And if you believe that you need to do a mesh excision of the mesh exposure following a sacrocolpopexy, what route would you go in to -- first to do that mesh rescission?
A. Again, that depends upon all the different factors and things. But I have to think back to, again, the last time we had one, which was roughly seven years ago, when we swapped over to IntePro.
Sacrocolpopexy meshes, you have to be careful what you're going after because that's a lot -- there's mesh that extends all the way up to the sacrum. So you're going to be then counseling the patient on as far as the dissection, if it's just limited, just cutting it out.
If -- now, I have not seen this in my practice, however, I've talked to my urogynecology colleagues about this. If you have a patient who comes in with, obviously, a purulent discharge, a large, gaping hole and a large amount of mesh coming back and the patient has systemic symptoms of

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infection, now you're probably going to be approaching that transabdominally.
Q. Is it correct that you would try to do a transvaginal mesh excision following a sacrocolpopexy if -- strike that.
Is it correct that you would first attempt -- let me see how I can say this.
If you have a patient who has a mesh excision following a sacrocolpopexy and it is a --
A. It's mesh exposure.
Q. Yeah. I'll just call it that. Yeah.
If you have a patient, Doctor, who has a mesh exposure following sacrocolpopexy and you believe that you can do the mesh excision transvaginally or transabdominally, which option do you choose?
A. Well, I can always do it transabdominally. That's a major and morbid procedure. So the question is, can I accomplish it transvaginally? And that's when all those other criteria I talked

Page 403

about, the patient-specific issues.
Q. So it's correct, then, that if you can do a transvaginal mesh rescission, you prefer to do so over the transabdominal mesh excision; correct?
A. If it can be safely and successfully accomplished transvaginally, that is, no question, my preferred route.
Q. And that's because transabdominal surgery is a major and morbid surgery; correct?
A. That is fair to say, yes.
Q. Before becoming involved in this litigation, had you ever looked at mesh that had been removed from a patient under a microscope?
A. No.
Q. Have you done that since becoming involved in this litigation?
A. Not of my own patients. I've seen photographs and microscopies and papers.
Q. Prior to being engaged as an expert witness in this matter, had you ever performed any examination of the porosity of

Page 404

meshes?
A. No.
Q. You don't hold yourself out to be a polymer chemist; correct?
A. That is correct.
Q. If you were counseling a patient on the sacrospinous ligament fixation surgery, what risk would you identify to her with that procedure?
A. Well, I wouldn't have that counsel, consultation because I would send them to my urogynecology colleagues.
Q. Because you don't do sacrospinous ligament fixation procedures; correct?
A. That is correct.
Q. Can you tell me what independent research you did in connection with your role as an expert in this litigation, other than reviewing the materials that plaintiffs' counsel provided to you?
A. Well, I reviewed, as you mentioned, the internal documents, I reviewed roughly, what, 200 manuscripts, scientific journal manuscripts, and then the depositions, which would be the -- from the

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litigation.
Q. The internal documents were documents that Mr. Anderson or the other plaintiffs' lawyers gave you; correct?
A. Correct.
Q. Before becoming involved in this litigation, had you ever reviewed any other company's internal documents?
A. Only pertaining to that patent infringement case.
Q. The deposition transcripts, those were given to you by Mr. Anderson or plaintiffs' counsel; correct?
A. Correct. Yes.
Q. The medical literature, the manuscripts that you reviewed, were those given to you by plaintiffs' counsel as well?
A. They gave me a few. So roughly we're looking at 200 or so manuscripts in my report and supplemental report. When this all started, I believe Mr. Anderson gave me 20, maybe 30. So everything else is from me.
Q. So the independent research you did besides reviewing the materials that

plaintiffs' counsel sent to you was you reviewed some of the medical literature and manuscripts.
A. Yeah. It's fair to say that except for what I received from Mr. Anderson and colleagues, everything would be journal reviews.
Q. Do you know any of the study investigators involved in clinical studies concerning Gynemesh® PS?
A. No, I -- I don't know any of those.
Q. Do you know Doug Hale?
A. I don't recognize the name.
Q. Do you know anyone involved in the Prolift® clinical studies?
A. Not that I know of, no.
Q. Now, you've never been employed by the FDA; correct?
A. No.
Q. I'm not correct?
A. No. You are correct. I have never been employed --
MR. ANDERSON: Your bad question.

THE WITNESS: -- or never anticipate being employed by the FDA.
BY MR. SNELL:
Q. Have you ever been a consultant to the FDA?
A. No. The closest would be through that Public Citizen, Ralph Nader's group, where I had comments read at the FDA. But I wouldn't think I would be a consultant for.
Q. Has the FDA ever paid you to be a consultant to provide information to them?
A. No.
Q. Have you ever served on an FDA advisory committee board?
A. No.
Q. Have you ever testified at any government institution, setting aside, you know, the patent case and any other depositions or trial testimony you've given?
A. No.
Q. Have you ever testified at an FDA advisory committee?
A. No. Again, other than that Public Citizen comments. But I was not personally there.

Q. Have you reviewed the federal regulations that pertain to medical devices?
A. No.
Q. Have you ever reviewed any FDA regulations pertaining to devices before becoming engaged as an expert witness in this case?
A. No.
MR. ANDERSON: Off the record.
(Discussion off the record.)
BY MR. SNELL:
Q. Have you ever been involved in the clinical trial designed to evaluate the safety and efficacy of a medical device? When I say clinical trial, I mean in humans.
A. Yes.
Q. What was that?
A. 1998 to '99, it was a new design of an artificial urinary sphincter for men, and I was involved in the original dog studies and then it went into human trials, which my name was on. However, I was not involved because I went down to my fellowship. But my name would be attached to it.

Q. So it's correct that you were not involved in the human clinical trials with regard to this artificial urinary sphincter; correct?
A. I was not involved in the implantation. I was involved heavily as far as the write-up, the documentation. And then timing, I was sent down to my fellowship so I left. I did the work but didn't get to do the surgery.
Q. You've never been involved in a clinical trial designed to evaluate the safety and efficacy of a prolapse device; correct?
A. Correct.
Q. You've never been involved in a clinical trial designed to evaluate the safety and efficacy of a stress urinary incontinence synthetic sling; correct?
A. Correct. I have not.
MR. SNELL: Why don't we take a break.
(Recess, 11:15-11:52 a.m.)
BY MR. SNELL:
Q. Doctor, you've never been

involved in a clinical trial designed to assess the safety and efficacy of a stress urinary incontinence device; correct?
A. Correct.
Q. Prior to becoming involved in this litigation, you had never reviewed a device design safety assessment; correct?
A. From an industry, I guess I don't know -- I just want to make sure I'm clear in understanding your question.
Q. Yes.
A. Would this be an industry --
Q. From a manufacturer, yes.
A. No, I have not.
Q. You're not an FDA regulatory expert, are you?
A. No, I'm not.
Q. Yesterday, Doctor, you mentioned the Iglesia study?
A. Yes.
MR. SNELL: Can we mark it as the next exhibit.
(Exhibit Elliott-9 was marked for identification.)
BY MR. SNELL:

Q. Doctor, I've handed you Exhibit Number 9, which is the Iglesia randomized, controlled trial in which you referred to yesterday; correct?
A. Yes.
Q. And you know that in this study only 65 women were ultimately recruited into the study; correct?
A. That is correct.
Q. And of those, there were 32 women who received mesh placement; correct?
A. Yes.
Q. And the 32 women were recruited between January 2007 to August 2009; correct?
A. That is correct.
Q. You mentioned the mesh exposures with this study yesterday in your testimony; correct?
A. That is correct.
Q. Turn, if you would, Doctor, to the bottom of Page 298.
A. (Witness complies.)
Q. And do you see it says, "Of the 32 mesh patients, five developed erosions"?

Do you see that?
A. Yes.
Q. Now, this is something that we've discussed over the course of your deposition, the terminology of exposure versus erosion; correct?
A. Correct.
Q. As you look at these data in this study, these are not mesh erosions, as you would call them, such that they eroded into another organ like bladder; correct?
A. From my recollection -- I'd have to go look at it specifically because, again, that nomenclature is confusing. My recollection is that they were what we call now extrusions or exposures.
Q. I didn't know if you were continuing.
A. Oh, no. No. I was waiting for you. I'm sorry.
Q. On Page 299, Doctor --
A. Yes.
Q. -- it discusses the treatment of these mesh exposures; correct?
A. Let me just -- yeah. No. That's

where I'm -- I'm just seeing what their treatment was. Yes, it does discuss that, what they did.
Q. Three of them required a procedure in the operating room to remove the mesh; correct?
A. Oh. Three, I missed it. Yes, three of the five required procedures in the operating room. Yes, you are correct.
Q. And the other two exposures, one was described as small and resolved after in-office trimming; correct?
A. Yes.
Q. And local estrogen use; correct?
A. Correct.
Q. And one of the exposures was persistent but not symptomatic enough to require intervention; correct?
A. Correct.
Q. A little further down, in the next paragraph, it's correct that none of the patients in the Prolift® group had a major infection, requiring use of postoperative antibiotics; correct?
A. Well, it says here one patient in

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each group had a febrile illness while hospitalized, and that would usually mean you're going to have to -- you're going to give antibiotics. So your question was --

Q. My question is, the authors report that none of the Prolift® patients had a major infection, requiring use of postoperative antibiotics; correct?

A. Major infection. Well, that's what it says there but that's not congruent with what they say, one patient in each group had a febrile illness while hospitalized.

You don't get a fever unless you have an infection. So I see what you're saying but I see incongruency in the data. If I were reviewing this manuscript, I would say I need clarification.

Q. Well, only one patient in the Prolift® group had a febrile illness while hospitalized; correct?

A. That is correct. That's what they assess, yes.

Q. And only one patient in the non-mesh group -- strike that.

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And one patient in the non-mesh group had a febrile illness while hospitalized; correct?

A. That is correct.

Q. And the rate of febrile illness while hospitalized with Prolift® was not higher than that with the non-mesh group; correct?

A. Well, statistically speaking, it was higher because there are 32 in mesh and 33 in the non-mesh so one patient in each, statistically speaking, would be different. But I know what you're saying.

MR. SNELL: No. Move to strike.

BY MR. SNELL:

Q. One patient in each group had a febrile illness while hospitalized; correct?

A. That is correct, yes.

Q. And there was 32 patients in one group and 33 patients in the other group; correct?

A. That is correct.

Q. And are you saying that there is a statistically significant difference

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between that one febrile illness in each group?

A. What I'm saying is there is a percentage, you're correct, not statistically significant, but there's a percentage difference just because one out of 32 is different than one out of 33.

MR. ANDERSON: You asked about the rate of illness, not the number of illnesses. That's what he was referring to.

MR. SNELL: Okay.

BY MR. SNELL:

Q. The number of febrile illnesses was not different for the Prolift® versus the non-mesh group; correct?

A. Correct. Just because when I review manuscripts, which I take a lot of pride in, and hence The Journal of Urology awarded me the award as far as the best reviewer in female urology, that's why I just, when I hear words, I want to be more specific about it.

Q. And the difference between one in 32 and one in 33 is what?

A. I'd have to get a calculator and

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do it, the difference.

Q. One in 33 is 33.33 repeating percent; correct?

A. Yes.

Q. One in 32 is 31.25; correct?

A. I'll take your word for it.

Q. There's no statistically significant difference reported between these febrile illnesses in the two cohorts; correct?

A. They do not report it, no.

Q. What are the reasons why a patient would develop a febrile illness?

A. There will be many potential reasons, so it's going to be difficult to narrow it down to just a few.

It could be a complication of surgery itself, bowel perforation, bladder perforation, wound infection, rectal injury, sigmoid injury, atelectasis, pulmonary embolism, stroke. You know, there's a -- there's an extensive list.

Q. Can you, as you look at this paper by Iglesia, Dr. Sokol and others, can you tell me, see the percentage of patients

who developed mesh exposure was 15.6 percent; right?
A. Yes.
Q. And the study was stopped because the rate of mesh exposure was more than 15 percent; correct?
A. Yeah. Again, I'd have to look at the paper specifically but --
Q. I'm on Page 302.
MR. ANDERSON: Right here (indicating).
THE WITNESS: 302. Yeah.
BY MR. SNELL:
Q. It says, "Weakness include the short follow-up and lack of statistical power due to premature stopping as a result of reaching predetermined mesh erosion rates of more than 15%."
Do you see that, Doctor?
A. Yes.
Q. So the study was stopped because of the exposure rate of more than 15 percent; correct?
A. Yes. They had a -- they had a predetermined threshold once crossed, it

would be terminated, and I would imagine that was established by an ethics committee.
Q. And as you look at this paper, do you know what the rate of erosion was in the non-mesh group?
A. In the non-mesh group? I would have to look through it. I don't -- I don't recall.
Q. Would you expect the rate of suture erosion to be reported in this study?
A. Again, I would have to look at the paper, see how they did their anterior colporrhaphies or the prolapse repairs.
Many surgeons, including myself, do not use permanent sutures so erosion is -- or extrusion is not an issue. I don't recall how they did their repairs.
Q. If the rate of suture erosion was 15 percent or more, would you expect it to be in this paper by Dr. Iglesia?
A. I think it should be reported, yes. But I see the sutures they used in here. They used absorbable -- oh, PDS. Well, I don't know what size they used. PDS. That's what I use. And also they do

use polytetrafluoroethylene.
Q. Is that Gore-Tex?
A. Yes. That's for their culdoplasties, according to what they say here.
Q. One of the other articles you mentioned yesterday was the Withagen paper; correct, Doctor?
A. Yes.
Q. And that being the Withagen randomized, controlled trial; correct?
A. Correct.
(Exhibit Elliott-10 was marked for identification.)
BY MR. SNELL:
Q. Doctor, you've been handed Exhibit Number 10. Is this the randomized, controlled trial by Withagen to which you referred yesterday in your deposition?
A. Yes.
Q. And this was a study of the use of Prolift® versus conventional vaginal repair; correct?
A. Correct.
Q. And the cohort of patients were

those who had recurrent prolapse; correct?
A. Yes.
Q. And ultimately, 97 women underwent conventional repair and 93 underwent the Prolift® repair; correct?
A. Yes.
Q. And there was a 98 percent follow-up rate at one year; correct?
A. 93 -- excuse me. I'm sorry. Can you repeat that again? I'm sorry.
Q. Sure. There was a 98 percent follow-up rate after 12 months; correct? In the "Results" section.
A. Yes.
Q. 12 months, so -- strike that.
One year after surgery, anatomic failure in the treated compartment was observed in 45.2 percent of the conventional vaginal repair group; correct?
A. That is correct.
Q. And one year post surgery anatomic failure in the treated compartment was observed in only 9.6 percent in the Prolift® group; correct?
A. Correct.

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Q. And that difference was statistically significant; correct?
A. It's a very significant anatomic difference, yes.
Q. Turn, if you would, Doctor, to Page 247. And I'm on the left column in the text. Let me know whenever you're ready.
A. Left. Yeah. Uh-huh.
Q. On Page 247 the study authors report, in the conventional group failure rates were higher in both anterior as well as in the posterior compartment compared with the tension-free vaginal mesh group, citing Table 5; correct?
A. That is correct. They were referring to anatomic failure.
Q. Correct. And if we look at Table 5, where they're looking at POPQ stage two or greater failure; correct?
A. They don't say POPQ. I would assume they would have used POPQ, though. I'd have to go to Table -- where they refer to Table 5. For it to have gotten published in 2011, it has to be POPQ.
Q. So in all patients at six months

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the vaginal mesh Prolift® group had a lower rate of POPQ failure; correct?
A. Correct.
Q. And in all patients at 12 months there was a lower rate of POPQ failure at 12 months; correct?
A. Yeah. Correct.
Q. I think I said that twice. Let me just back up.
In all patients at 12 months there was a lower rate of POPQ failure in the Prolift® group compared to the conventional group; correct?
A. That is correct.
Q. And for those patients undergoing anterior compartment repair at six months there was a lower rate of POPQ failure for the Prolift® group as compared to the conventional group; correct?
A. Correct.
Q. And at 12 months for those patients undergoing anterior repair there was a lower rate of POPQ failure with the Prolift® group compared to the conventional group; correct?

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A. Correct.
Q. At one year in the anterior compartment cohort there were 7.8 percent POPQ failures in the Prolift® group; correct?
A. Yes.
Q. And there were 55.1 percent failures in the conventional non-mesh group; correct?
A. Correct.
Q. There was a lower rate of POPQ failure in the posterior compartment for Prolift® compared to the conventional non-mesh group; correct?
A. Where are you at? Six months or at -- you're at 12 months?
Q. I'm at both of them.
A. Okay. Yes.
Q. P value is less than .05; correct?
A. Yes. And then you left out apical at 12 months, conventional versus mesh. Maybe it was an oversight.
Q. In the apical, in the apical compartment there was no statistically

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significant difference; correct?
A. No. They had equal results, anatomic, POPQ.
Q. Why don't we look at Table 3.
A. Okay.
Q. For pain in the lower abdomen or genital area, do you see that?
A. Yes, I do.
Q. There was no difference between Prolift® and the conventional repair; correct?
A. When limited to 12 months, you are correct.
Q. Well, there was no statistically significant difference in de novo pain between Prolift® and conventional surgery in this study; correct?
A. At 12 months, you're correct.
Q. And there was no significant difference between dyspareunia seen for Prolift® versus the conventional group; correct?
A. Correct. And they must have discussed symptomatic results in here somewhere too. Because, as we mentioned, we

have to also look at the patient in totality. Anatomy alone is not sufficient.
MR. SNELL: Objection. Move to strike.
MR. ANDERSON: He didn't --
MR. SNELL: I don't have a question pending.
MR. ANDERSON: He doesn't want to ask you about that.
THE WITNESS: I was continuing to think.
MR. ANDERSON: He doesn't --
THE WITNESS: I'm not supposed to think anymore?
MR. SNELL: You're here to answer my questions. I know you have your opinions and prerogative, and I hear you.
THE WITNESS: Understood.
BY MR. SNELL:
Q. Since you did bring up symptomatic, in the Withagen paper there were symptomatic improvements in the Prolift® group; correct?
A. Absolutely. Roughly 80 percent.
MR. SNELL: Let's go off the

record.
(Discussion off the record.)
BY MR. SNELL:
Q. Doctor, I believe you earlier testified that before you became involved in this litigation, you had not looked at any pathology slides of mesh; correct?
A. I've seen, well, gross photographic specimens from patients that I have explanted. But pathology study, you mean microscopic slides, is that what you're referring to?
Q. Yes.
A. Probably at lectures. But it would be fairly limited.
Q. Yesterday you recall two patients for Prolift® for whom you had treated for complications; correct?
A. Correct.
Q. And in your treatment of those patients you did not see degradation of the mesh, did you?
A. Well, what I'm describing as far as degradation, I don't know if these are extrusion individuals. In those

individuals, I mean, I can't recall specifically.
What I'm referring to as degradation is the gross inspection. It's brittle, firm, breaks easily when you touch it or if a clamp is put on it. To me, I'm calling that degradation. But that's coming from a clinician's perspective, not a biomaterials expert or pathologist's perspective.
Q. And for the two Prolifts® that you recall, did you believe that they were degraded?
A. I can't -- to be specific, I can't recall the specifics on that.
Q. In your report you cite to a paper by Costello, 2007, with regard to degradation?
A. Yes.
Q. You know the Costello paper was not a paper about the Prolift®; correct?
A. It was about polypropylene in general. To answer your question, yes.
Q. The mesh analyzed in the Costello paper was not the exact same mesh used in

Prolift®; correct?
A. Well, I would have to look at the manuscript to know which products were used. All I can recall is that it was polypropylene.
Q. You mentioned a Dr. Donald Ostergard?
A. Yes.
Q. Do you know him?
A. I've had correspondence with him a long time ago, I believe probably even when I was a resident, concerning writing a paper. In fact, I recall now, it was an artificial urinary sphincter in women. He contacted my chairman of my department, I was a resident, I had correspondence with him, and that would have been 12, 14 years ago. But nothing since then.
Q. Do you know whether he is an expert for the plaintiffs' lawyers in the mesh litigation?
A. I have not heard that he is. I have no knowledge of that.
Q. The 2010 article by Clave --
A. Yes.

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Q. -- you don't know how many, if any, of those 100 explants in that study were Prolift®; correct?
A. No, I don't. From my knowledge, all I know is they were polypropylene. I'd have to review the manuscript to determine that.
Q. The barbed-wire effect that you note on Page 58 --
A. Yes.
Q. -- that is a quote from Dr. Klinge; correct?
A. Actually, I don't know if that's his or mine, because I felt that. So I would have to -- if I give a reference, 88. I don't know if Dr. Klinge said it. I -- I don't recall when I wrote this if I was quoting, just making the -- putting aside because that's what I have felt. He may have said the same thing also.
Q. When you say that is what you had felt, what do you mean by that?
A. Meaning when I've taken explants of mesh material, it's this friable, broken, you can -- that's why when I instruct the

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residents, you have to look and feel for the mesh. And many times, it's so encased in scar that you have to go by feel, then you can feel the poking sensation of it. It's sharp.
Q. And in the Prolift® mesh that you have examined, you don't recall it being barbed wire; correct?
A. No. I cannot recall. I did not keep records if it was specifically Prolift®. I do know specifically TVT® but not Prolift®.
Q. Can you tell me any clinical human studies in TVT® that reported a barbed-wire effect with the mesh?
A. I don't recall off the top of my head, no. Barbed wire is a descriptive term, not a scientific term.
MR. SNELL: Okay. Let's have some lunch.
(Luncheon recess, 12:29-1:15 p.m.)
AFTERNOON SESSION
BY MR. SNELL:
Q. Am I correct that you never

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looked at any FDA guidance documents before becoming involved in this litigation?
A. I'm not familiar what guidance documents are.
Q. As you sit here today, do you know what FDA guidance documents are?
A. No, I do not.
Q. Do you know whether the mesh that was used in sacrocolpopexies by surgeons between the 1970s and the 1990s, whether that use was cleared by the FDA for use in prolapse?
A. I do not know that.
Q. The FDA has never begun, to your knowledge, any type of enforcement proceedings against Ethicon for the Prolift®; correct?
A. I don't know. Proceedings, again, that falls under regulation territory. I'm a clinician. I know of the only -- the event in I believe 2008 where letters were sent, from what I reviewed in depositions, about not having 510 clearance. But I'm not a regulatory individual.

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Q. You're not a regulatory expert on 510(k) clearance.
A. By no means.
Q. And you're not a lawyer; correct?
A. No.
Q. You don't have any legal specialization in what is illegal versus legal conduct; correct?
A. Correct.
Q. I'd like to ask you a couple of questions, Doctor, about Exhibit Number 2.
A. Yes.
Q. And this is your November 7th, 2012, supplemental report; correct?
A. Yes, it is.
MR. SNELL: And, again, for the record, we have filed a Motion to strike this report and identified the bases for that. And I'm not waiving any arguments or rights by questioning the doctor on this report.
BY MR. SNELL:
Q. Doctor, in your November 7th, 2012, report, this is the first time that you identified any opinions with regard to

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Mrs. Gross; correct?
MR. ANDERSON: Objection.
Asked and answered.
Go ahead.
THE WITNESS: Correct.
BY MR. SNELL:
Q. And the opinions you offer in this report consist of one paragraph with regard to Mrs. Gross; correct?
A. Well, two paragraphs in which her name is mentioned, one paragraph specific to her.
Q. There's one paragraph where you set forth opinions with regard to Mrs. Gross; correct?
A. Yes.
Q. And you referred -- I'm sorry. Let me start over.
And you reviewed certain medical records of Linda Gross, as identified in this report?
A. That is correct.
Q. These were medical records of Linda Gross that were given to you by plaintiffs' counsel; correct?

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A. That is correct.
Q. When did you receive the medical records of Linda Gross?
A. I don't recall exact date.
Q. Give me your best approximation under oath.
MR. ANDERSON: Objection.
THE WITNESS: November 7th. I would -- this is a very rough guess because there was a flood of information coming to me. Roughly a month prior to this.
BY MR. SNELL:
Q. Now, you haven't reviewed all of Mrs. Gross's records; correct?
A. I have reviewed, covered the medical records and I believe there's depositions pertaining specifically to her that I've reviewed, so I can't say if I've read all because I don't know -- I don't know what I don't know.
Q. So you don't know if this is a complete list of all of the records by Linda Gross; correct?
A. What I can state --
MR. ANDERSON: Objection.

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Go ahead.
THE WITNESS: What I can state is what is on here is what I've reviewed.
BY MR. SNELL:
Q. And so it would be correct that you do not know whether this is all of Linda Gross's records, then; correct?
A. That is a fair statement, yes.
Q. And have you ever asked to look at all of Linda Gross's records?
A. No. I have requested Linda Gross's records. I don't know if I ever used the word "all."
Q. For Pamela Wicker, when did you receive her medical records?
A. It would have been roughly the same time as Miss Gross's.
Q. So roughly one month before your November 7th, 2012, report?
A. Correct. Yes.
Q. Do you know if you've reviewed all of Pamela Wicker's records?
A. Same answer as with Miss Gross. It would -- everything that is on this report is what I reviewed, so I don't know

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if there are other records out there.
Q. Did you ask to look at all of Pamela Wicker's records?
A. Again, I asked to review the records. I can't say I used the word "all."
Q. Now, at the same time you had these records for Linda Gross and Pamela Wicker and were working on your November 7th, 2012, report, you also had expert reports by the defense experts; correct?
A. That is correct.
Q. You also had the case-specific reports by the defense experts; correct?
A. Correct.
Q. You had other case-specific reports by other plaintiffs' experts already; correct?
A. Correct.
Q. Did you examine Mrs. Gross?
A. No.
Q. Did you ask to examine Mrs. Gross?
A. No.
Q. Did you examine Mrs. Wicker?
A. No.

Q. Did you ask to examine Mrs. Wicker?
A. No.
Q. Did you conduct any independent testing on Mrs. Gross?
A. No.
Q. Did you ask to conduct any independent testing on Mrs. Gross?
A. No.
Q. Did you conduct any independent testing on Mrs. Wicker?
A. No.
Q. Did you ask to conduct any independent testing on Mrs. Wicker?
A. No.
Q. If a patient has urinary dysfunction, what are the tests that you perform to come to that conclusion?
A. Depends upon the symptoms.
Q. Can you tell me the tests and the symptoms that would lead you to conduct such a test?
A. Well, it, number one, depends if it's a male or a female.
Q. Let's only focus on females.

A. Females. And then it depends upon the history as far as what they are presenting with, i.e., idiopathic symptomatology versus a causative factor. That's going to direct me if they've had surgery or not, what type of surgery they've had, also, the severity of the problem.

Then laboratory testing, urinalysis would affect the evaluations, past evaluations that have been done, the quality of the testing that had been done elsewhere, if any.

So I can't give you a simple answer because there's so many variables that go into the equation.
Q. Are there certain urinary tests that can be done to help determine the etiology of urinary dysfunction?
A. Yes.
Q. What might those be, Doctor?
A. Screening uroflow or post void residual check. That would just be an ultrasound to see if the bladder is elevated capacity -- excuse me -- elevated residual or does the bladder empty out or somewhere

in between.

The flow rate, how fast the urine can come out, the pattern on the flow rate, is the woman straining or does it appear to be a bladder contraction type of a flow?

Another study could be a urodynamics that looks at the function of the bladder, spelled U-R-O-D-Y-N-A-M-I-C-S, urodynamics, or cystometrogram is another term.

Again, that depends upon multiple different factors of what got the patient to see me. It's a fairly expensive study so I don't order them on everybody. And that evaluates the bladder, how much the patient can hold, the sensation levels, the -- their bladder spasms, bladder pain with filling. Then during the urination phase, is the bladder working or not to get the urine out? How much is left behind?

Other studies can be cystoscopy but, again, there has to be a reason why I'm going to do that. Other studies, possibly pelvic ultrasound versus transvaginal

ultrasound. Possibly a CAT scan of the abdomen and kidneys versus possibly an MRI. I think that's pretty much it.
Q. And in your report regarding Mrs. Gross did you identify any testing that was done on Mrs. Gross with respect to her urinary retention or dysfunction at any time?
A. Yeah. I'd have to go back and look at specifically all that was done. It was fresh in my mind when I wrote the report but I do recall, as I recall, there was a residual urine check, there may or may not have been cystoscopies. Again, for specifics for each individual, I'd have to check on that and look at the records again.
Q. Well, you didn't put the results of any residual urine check in your report; correct?
A. That is correct.
Q. You didn't put the results of any cystoscopy in your report; correct?
A. Yes -- well, yes, there is.
Q. Where is that, Doctor?
A. Mrs. Gross, last sentence, "I

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also note that the findings seen by Dr. Benson on cystoscopy were not 'interstitial cystitis.'"
Q. So other than the cystoscopy, you did not identify any other testing that Mrs. Gross had undergone.
A. I do not --
Q. Correct?
A. I do not state it in there, no.
Q. As you sit here today, do you recall the results of any urodynamic studies on Mrs. Gross?
A. I do not recall.
Q. Do you know whether urodynamic studies were even done on Mrs. Gross?
A. At this point in time right now, I cannot recall.
Q. Do you know the pattern on Mrs. Gross's flow rate, if any such testing was performed?
MR. ANDERSON: Are you just asking from memory or do you want him to look at records?
MR. SNELL: I'm asking him as he sits here and recalls --

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MR. ANDERSON: Okay.
MR. SNELL: -- based upon what he reviewed and what he did or did not put in his report.
THE WITNESS: As I sit here, going by memory, I cannot recall the specific studies that were done on her.
BY MR. SNELL:
Q. You reference the sentence where you opine that the findings seen by Dr. Benson on cystoscopy were not interstitial cystitis but, rather, due to urinary retention and irritation of the bladder by the Prolift® mesh.
Do you see that?
A. That's correct.
Q. What's your basis for that statement?
A. Well, with cystoscopy there are no pathognomonic findings for interstitial cystitis to the point that cystoscopies are not recommended in interstitial cystitis.
Any findings within the bladder are not consistent to rule out or include, and by exclusion, interstitial cystitis

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cannot have any other concurrent pathology in the pelvis and bladder, so the findings, based upon that, were consistent with the irritation and previous surgeries and the mesh.
Q. Can you rule out interstitial cystitis in Mrs. Gross's case, based upon what you've reviewed?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: Can I rule out interstitial -- yes, actually, I can. The diagnosis -- the most recent criteria from a paper by Hanno, et al., H-A-N-N-O, which is in my supplemental report, make sure I -- yeah, Hanno, this is written by Hanno, the last to the bottom, "Interstitial Cystitis - Epidemiology, Diagnostic Criteria, Clinical Markers."
In that manuscript and others as far as from the International Continence Society, you cannot have interstitial cystitis when there's other concurrent pathology present, as which was stated in Doctor -- pertaining to Doctor -- excuse me.

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Pertaining to Mrs. Wicker in the deposition by Dr. Raz, it says my opinion and his are the same. So I can rule out interstitial cystitis.
MR. SNELL: I'm going to move to strike the stuff about Mrs. Wicker because my question was focused on Mrs. Gross. I'm going to move to strike the testimony concerning Mrs. Wicker in that answer since my question pertained to Mrs. Gross.
BY MR. SNELL:
Q. What is -- are there diagnostic criteria for diagnosing interstitial cystitis?
A. Yes.
Q. And who puts out those criteria?
A. Well, that would be a consortium of physicians in the various different societies. Most likely, I believe, the International Continence Society. I'd have to look at that.
In the reference the Hanno paper was talking about the -- this consortium and the latest diagnostic

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criteria. So that is not decided by one person; it's a consortium.
Q. And what are the diagnostic criteria for interstitial cystitis?
A. I would need that paper to be thorough, so if we have that paper, that would be the best.
From memory, you have specific bladder pain with filling, tends to be relieved by urination, you do not have generalized pelvic pain, acute onset of urgency to urinate with leakage usually rules out IC. Those are off the top of my head. The paper is much more thorough.
Q. The statement where you make that one cannot have interstitial cystitis if other concurrent pathology is present, what do you mean by other concurrent pathology?
A. Meaning an etiology for bladder dysfunction.
Q. Can you explain that in laymen's terms?
A. Like an example would be a urinary tract infection, surgery, trauma, something else that can be causing it.

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Interstitial cystitis is a diagnosis of exclusion. What that means is you rule out everything else and if you can't find anything and they meet the pain symptom criteria, pain with filling, relieved by urination are the classic ones, then that's interstitial cystitis because there is no biopsy, there is no cystoscopy, there is no imaging that -- used in the diagnosis of IC.
Q. What objective testing on Mrs. Gross's case showed irritation of the bladder by the Prolift® mesh?
A. Well, that's the cystoscopy.
Q. Did the cystoscopy report that there was Prolift® mesh in the bladder?
A. I don't recall. I'd have to look at it. But I do not recall erosion being a factor, no.
Q. What objective testing showed urinary retention by the Prolift® mesh?
A. Well, I mean, an elevated residual urine.
Q. Is an elevated residual urine a finding that's specific to Prolift® mesh or

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can that be from other causes?
A. There can be other causes.
Q. Can an irritation of the bladder occur with other causes besides Prolift® mesh?
A. In the situation of a urinary tract infection, yes.
Q. Is urinary tract infection the only other thing that would cause irritation of the bladder?
A. No. There would be other issues, other things.
Q. Like what?
A. Fistula formation, again, trauma, surgery, foreign body, stones.
Q. When did Mrs. Gross first have urinary retention symptoms?
A. I would have to review the records.
Q. There was a delay in the onset of Mrs. Gross's urinary retention symptoms; correct?
A. As I recall, yes.
Q. Do you recall how long that delay was?

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A. Off the top of my head, no.
Q. How is injury to the pelvic neuroanatomy objectively diagnosed?
A. Pelvic neuroanatomy is incredibly complicated and it's still evolving as far as the thought process on it, but objective evidence would be clinical symptomatology, probably urodynamics, and then chronologic association with events.
Q. Are there particular tests that one can do to diagnose pelvic -- I'm sorry -- to diagnose injury to the pelvic neuroanatomy? And when I say tests, I'm talking about diagnostic testing like nerve testing or something like that.
A. No, you cannot do -- EMGs I doubt would be sufficient. There is no way to do an EMG of small nerve fibers, only large nerve fibers, so you can't do EMG. The closest would be the urodynamics or cystometrogram.
Q. What is a cystometrogram?
A. The same thing as the urodynamics. They're synonyms. CMG or UDS for abbreviations is a whole lot easier to

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say.
Q. Did Mrs. Gross undergo urodynamics?
A. Either Miss Gross or Miss Wicker did. I cannot recall off the top of my head. I'd have to look at the records again.
Q. Did Mrs. Gross have any urinary problems before her Prolift® implantation?
A. Again, I'd have to go back to the records to review that because I can't recall.
Q. You know that she had a long history of stress urinary incontinence.
A. Again, I'd have to go back to the records and...
MR. ANDERSON: I'm happy to go to try to grab any record that you would like for him to refer to, Burt. Counsel.
BY MR. SNELL:
Q. You did not in your expert report regarding Mrs. Gross state an opinion about whether Prolift® was a proper surgical option to offer by her surgeon, did you?
A. That is correct. I did not.

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Q. And as you -- do you plan to offer an opinion at trial as to whether Prolift® was an appropriate surgical option to offer to Mrs. Gross by her doctors?
A. No. I was instructed, was Prolift® a causative factor in the voiding dysfunction, not whether or not the Prolift® was the correct treatment or not.
Q. So the only opinions you plan to offer at trial is in connection with the analysis of was Prolift® a causative factor in any urinary problems with Mrs. Gross. And I'm talking about opinions specific to the Gross case.
A. Sure. I understand.
Q. Is that correct or not?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: Well, unless somebody asks me, was it the correct thing? But I'm not volunteering that information. Because my understanding when asked to review Gross and Wicker, it was specifically what caused their voiding dysfunction.
BY MR. SNELL:

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Q. In your report regarding Mrs. Gross and Mrs. Wicker you have not identified any criticism that you have with regard to her doctors; correct?
A. Correct.
Q. And you don't plan to offer at trial any criticisms about treatment provided by her doctors; correct?
A. Well, only if somebody asks me a question, I can't just sit there. So I'm not -- again, my job was, what caused their voiding dysfunction? If you or someone else asks me specifically, I guess somebody will object. I don't know what the answer is to that, I mean.
Q. This is the predicament I'm in, Doctor: You didn't issue any opinions in that regard.
A. Correct.
Q. And I'm not going to sit here on the second day of your deposition and ask you about opinions for which you haven't formulated and offered in this litigation.
I'm just trying to understand and make sure that at the time of trial you

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don't plan to come out and start talking about things that Mrs. Gross's doctors did incorrectly.
A. From what I understand, just so we're very, very clear, my opinion on Gross and Wicker as outlined in here is specifically to their voiding dysfunction and what I felt caused it.
MR. ANDERSON: So unless you ask him or one of your team asks him those questions, I can't control what you guys may ask. My team is not going to ask him those questions, those specific ones that you're referencing.
MR. SNELL: Okay.
MR. ANDERSON: Out of fairness to you. I understand where you're coming from.
MR. SNELL: Okay.
MR. ANDERSON: We want to be offering him for the specific reason that he just stated.
MR. SNELL: So in the Gross and Wicker cases, Dr. Elliott is being offered to testify and opine about the voiding

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dysfunction that Mrs. Gross and Mrs. Wicker has, according to his opinions, and the cause thereof.

MR. ANDERSON: And voiding dysfunction encompasses a number of things, pelvic neuroanatomy, damage to that area, a number of things that you can ask him about in terms of exploring his opinions as to what is related to that general opinion of voiding dysfunction or pelvic -- sustained injury to the pelvic neuroanatomy or neurologic function, et cetera.

But I think you're homing in on the area in which we've asked him or will ask him to opine.

BY MR. SNELL:

Q. Urinary dysfunction can be a potential complication of numerous prolapse surgeries other than Prolift®; correct?

A. Yes.

Q. Persistent pain is a potential complication with other prolapse surgeries besides Prolift®; correct?

A. Yes.

Q. When you say the injuries caused

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by the Prolift® -- I'm just going to read the whole sentence.

A. Yes, I see it.

Q. You state, "The injuries caused by the Prolift are appear to be permanent"; correct?

A. Yeah. That's an error. It should say the injuries caused by Prolift® appear to be permanent. That "are," A-R-E, should not be there.

Q. When you say the injuries caused by Prolift® appear to be permanent, are you talking about her voiding dysfunction?

A. I'm talking about the -- the pain, pelvic floor myalgia --

Q. Hold on.

A. -- and voiding dysfunction.

Q. When you say the pain, what pain are you referring to?

A. Pelvic pain.

Q. Is this pelvic pain specifically associated with voiding dysfunction?

A. Can be.

Q. In Mrs. Gross's case, I'm asking you, is this pelvic pain you're discussing

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specifically tied to her voiding dysfunction or is this pelvic pain like one can see with other forms of prolapse surgery?

A. No. We're talking a different -- it is -- it is in the continuum. Pain in and of itself can cause urinary retention, voiding dysfunction. Pain can be a sign of irritation within the pelvic neuroanatomy where there's other nerves like the vaginal plexus being irritated.

So it becomes a very complicated issue. That's why -- that's why people do what I do as far as taking -- doing fellowships I do, because this is very complicated.

Q. What's your opinion about Mrs. Gross's pelvic pain?

A. That she has a lot of it.

Q. Anything else?

A. That it appears to be a -- the causative factor is the surgery itself and the implantation of the Prolift® and the subsequent treatments have set off a cascade of pelvic floor dysfunction.

Q. You know Dr. Weber opines on that

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subject, pelvic pain, in Mrs. Gross?

A. I believe I read that, yes.

Q. You know Dr. Margolis opines on that same subject, pelvic pain, in Mrs. Gross.

A. Yes.

Q. Pelvic floor myalgia, what is that?

A. It's a descriptive term just saying that the pelvic floor, the neuro -- excuse me -- the musculature hurts. That's all it is is a descriptive term. It's not pathognomonic of a specific etiology but it's saying the entire pelvic floor hurts.

That's what -- or are inflamed. That's what myalgia means is inflamed muscles, basically.

Q. One of the ways that you can treat pelvic floor myalgia is to send the patient to special therapy to treat that problem; correct?

A. You're correct.

Q. Has Mrs. Gross ever undergone that specific therapy to treat pelvic floor myalgia?

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A. I know in reviewing the records, specifically the Mayo records and Dr. Trabucco, that it was offered at Mayo.
Q. What opinions are you going to offer about her pelvic floor -- strike that.
What opinions are you going to offer about Mrs. Gross's pelvic floor myalgia?
A. Depends upon the question I'm asked.
Q. Well, I want to know what you're going to offer because all I have is one paragraph, Doctor. So tell me.
A. Well, that I have to look at the chronology of her pelvic floor myalgia. Did she have it preop versus postop? If there were evidence that she had pelvic floor myalgia preop and it continued in the same intensity postop, then surgery was not a causative factor.
If she had no pelvic floor myalgia preop, then postop at some point in time developed severe pelvic floor myalgia, then I have a causative factor.
Q. As you sit here today, Doctor, in

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this deposition, have you formed an opinion to a reasonable degree of medical certainty whether the surgery was a causative factor in pelvic floor myalgia?
A. From my recollection of the records, she did not have significant or any pelvic floor myalgia preoperatively. Again, I'd have to review the records for that to make sure. And from my recollection, it all began after surgery.
MR. ANDERSON: And, again, I'll offer to get whatever record that you would like for me to try to get in the room next door, Counsel.
(Discussion off the record.)
BY MR. SNELL:
Q. Do you have any opinions on how Mrs. Gross's pelvic pain should be treated?
A. Having seen these patients extensively, this is a very difficult situation.
My review of Dr. Trabucco's management of the patient appears to be appropriate and I don't have any further ways of altering the situation.

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Q. With regard to Mrs. Gross's pelvic floor myalgia, do you have any opinions on how that should be treated?
A. I personally send these patients to a physical medicine and rehab for pelvic -- we have a pelvic floor myalgia clinic.
Q. And that's a pelvic floor myalgia clinic at Mayo --
A. Correct.
Q. -- or some other location?
A. Sorry. Yes, it is at Mayo. But, unfortunately, for most patients it's physically impossible for them to stay just because it's a prolonged evaluation and treatment. Individuals who are local can do it but ones far away cannot do it.
Q. How long is the treatment course, Doctor?
A. Very good question. It depends upon the patient. The three physical therapists I use, the first consultation is three hours, where they evaluate the individual's overall situation, their strengths and their weaknesses, where the pain is.

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And then they will either have a one-week intensive therapy sessions, which usually they don't do, more likely it's usually spread out over eight weeks, it's one treatment a week, hence, the reason why it's difficult for people from a long ways away to stay.
Q. How is voiding dysfunction treated?
A. Again, that's a complicated situation. Voiding dysfunction is a descriptive term of anything bad that can go on, running a spectrum from a bladder that does not empty out to one that empties out too much. And so the treatment is dependent upon the problem or the symptoms.
Q. Mrs. Gross's voiding dysfunction, in your opinion you say appears to be permanent; correct?
A. Correct.
Q. Voiding dysfunction can improve over time; correct?
A. Depending upon the etiology, yes, that is a possibility.
Q. Post surgical voiding dysfunction

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can improve over time; correct?
A. It depends upon the surgery. Radical hysterectomy, colon surgery, it does not improve over time. Smaller surgeries, yes, there's a chance. So, again, I have to be specific. I'm not trying to be difficult. I have to be specific to the cause.
Q. Post prolapse surgery voiding dysfunction can improve over time; correct?
A. Again, it depends upon the surgery because prolapse surgery encompasses a lot of different types of surgeries. So native, non-mesh, yes, I've seen that recover. I've also seen it not recover.
Sacrocolpopexy, usually I don't see voiding dysfunction. And I don't have enough long-term experience to see what will happen with mesh long term.
Q. Can voiding dysfunction following a mesh prolapse surgery improve over time?
A. Specific transvaginal mesh?
Q. Yes.
A. I suppose it could.
Q. Can you rule out that Linda

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Gross's voiding dysfunction will not improve over time?
A. Can I rule out will not improve? Is that the same way as saying it's permanent or can I -- I guess I don't understand your --
MR. ANDERSON: Vernacular.
MR. SNELL: Yeah. That's fair.
BY MR. SNELL:
Q. You would agree that Linda Gross's voiding dysfunction may at some point down the road get better.
A. Again, correct. And that's why I put the word "appear" or "appears" to be permanent. But no, I cannot prove it will not at some point in time improve. We don't have that long-term data yet.
Q. And does she need to self-catheterize currently?
A. I don't know her current status.
Q. You would agree that at some point in the future with further treatment and the passage of time, she may not need to self-catheterize; correct?
A. Again, depends upon the etiology.

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If the etiology is disruption of the vaginal plexus, pelvic splanchnics, due to a degradation or inflammation, it will not.
If those nerves are still intact and the insult is removed, then there is the chance with time it will improve. I don't know that data and nobody knows that data yet.
Q. As you sit here today -- let me say, in your report you did not state that you believe to a reasonable degree of medical certainty that there was a disruption to the vaginal plexus and splanchnic nerve that you just said; correct?
A. I did not state in my report -- well, yeah, actually, I did. I said including the --
Q. Where is it?
A. The first line, I said -- it says with -- starts "with regard" and then it goes, you know, then the comma and the second says, "including injury to the pelvic neuroanatomy." So that is what I said.
The vaginal plexus is the

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nerves on top of the vagina extending to the bladder that include the sympathetic and parasympathetic nervous system. So if those were disrupted, cut or injured in any way, it is most likely it will be a permanent condition.
Q. Were those nerves disrupted? And if so, what's the testing or data that showed that?
A. She has a bladder that does not work. The only nerves that create bladder function is the vaginal plexus. So if the vaginal plexus, you know, if they are cut, the bladder won't work. So I guess your question was -- what was your question?
MR. ANDERSON: He wanted to know if disrupted was the first part.
THE WITNESS: Oh, okay. Were those nerves disrupted. We have evidence of a bladder that does not work, we have a mesh -- excuse me. We have a dissection in the region where those nerves are. We have a mesh that was put in.
We have a mesh that was multiply operated on and she has a bladder

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that does not work, so I have a lot of evidence pointing towards the fact that those nerves have been injured. If those nerves were perfectly intact, she would be able to urinate.
BY MR. SNELL:
Q. I think we got off on this tangent when I asked you about your opinion regarding the need to self-catheterize. I'm just trying to understand it because this is complex.
A. Neuroanatomy is very complicated.
Q. Is it correct that at some point in the future Mrs. Gross may not need to self-catheterize?
A. That is a possibility, yes.
Q. Is it correct that she may only need to self-catheterize in the future on an intermittent basis?
A. Yes, that is a possibility.
Q. And the self-catheterization is related to the voiding dysfunction; correct?
A. That is to treat the voiding dysfunction, which her specific voiding dysfunction is retention.

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Q. Are there different degrees of urinary retention?
A. Yes.
Q. Can you tell me from a medical standpoint what those degrees are?
A. Well, there's no -- not a defined but we can have an individual who cannot empty their bladder at all to individuals who empty, you know, a certain percentage of their urine.
Q. Is there any recognized gradation of the degree of retention associated with voiding dysfunction?
A. No. Technically, anything over 100 milliliters is elevated, and there's no gradation beyond that.
Q. Interstitial cystitis, what symptomatology can that condition manifest itself in?
A. Bladder pain with filling.
Q. When you say with filling, what do you mean by that?
A. That the bladder when empty or following urination, the pain is relieved or markedly subsides and then as the bladder

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fills up, as it stretches, it hurts.
Q. Did you see that Dr. Weber opined on Mrs. Gross's urinary dysfunction?
A. You said Mrs. Gross?
Q. Yes.
A. Yes.
Q. Did you see that Dr. Margolis opined on Mrs. Gross's urinary dysfunction?
A. Yes.
Q. And you saw those opinions before you finalized your November 7th, 2012, report; correct?
A. Correct.
Q. You saw that Dr. Weber and Margolis had issued opinions about Mrs. Gross's pelvic pain before you finalized your November 7th, 2012, report; correct?
A. Correct.
Q. You saw that Drs. Weber and Margolis issued opinions about Mrs. Gross's pelvic floor myalgia before you completed your November 7th, 2012, report; correct?
A. Correct.
Q. With regard to Mrs. Wicker, you

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have one paragraph in your report that outlines your opinions; correct?
A. Yes.
Q. And it's your opinion that Mrs. Wicker has bladder pain?
A. Yes.
Q. Urinary frequency?
A. Yes.
Q. And urinary urgency.
A. Yes.
Q. What's the difference between urinary frequency and urinary urgency?
A. Frequency is going frequently, just the sheer number of voids during the day. Urgency is the acute onset of needing to void. They're describing two separate voiding issues.
Q. How is urinary frequency evaluated?
A. Usually a voiding diary.
Q. Did you look at a voiding diary for Mrs. Wicker?
A. I looked at somebody's voiding diary. I don't recall whose it was.
Q. Is there a recognized method for

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coming to a diagnosis of urinary frequency?
A. Well, yeah. I think it may be a combination of things: A urinalysis to rule out infection and the concentration of urine, the voiding diary to actually document how frequent it actually is, and I believe that would be it.
Q. Is there specific criteria for diagnosing urinary frequency?
A. No, there's not a set number of voids per day. No.
Q. Why is that?
A. Well, there is going to be a variation in the frequency of the day that is within the realm of a range of normal. It's like saying what's the appropriate foot size or how tall -- what is the correct height? That does not exist. There's a range that's acceptable or normal.
And so urinary frequency, a normal bladder holds 400 to 600 milliliters. A normal person, on average, consumes one to two liters of urine per -- fluid per day, so subsequently they're going to void a certain number of times.

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However, if they've been in a meeting drinking Coke and coffee all day, the frequency goes up. But, see, that's an aberrancy. That's why the voiding diary looks at multiple days.
Q. The 400 to 600 milliliters you referenced, that's the normal bladder capacity?
A. That's a range that is quoted as being somewhat consistent as being normal, yes.
Q. Is that in men or women or both?
A. Both. And there will be acceptable ranges outside of that. So it's not like it's clearly defined.
Q. For Mrs. Wicker, do you know how her -- how big of a woman she is?
A. No, I do not.
Q. Do you know what's the size of her particular bladder?
A. I don't know. I'd have to look back at the records and see what Dr. Raz said.
Q. And how is the size of a bladder determined?

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A. Well, if you performed a urodynamics, you would know because you would fill them up until they're full, or if you'd had what's called a uroflow where they urinate into a container, you'd be able to know at least how much they could hold on that event if they are full.
Q. Well, how do you know when they're full?
A. When they say I'm full. So you cannot perform urodynamics or uroflow on somebody who is cognitively impaired in any way. You're relying on the interaction of the patient.
Q. Can the size of a bladder differ in relation to the size of a woman, such that obese women tend to have larger bladders versus smaller-framed, normal weight or underweight women?
A. No, we know of no correlation that way.
Q. And so if a woman drinks fluids frequently throughout the day, there will be more frequency of urgency.
A. Not urgency but frequency.

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Q. So if a woman drinks fluids frequently throughout the day, there will be more urinary frequency; correct?
A. But just drinking frequently, if she's taking sips, that will not. You have to look at -- that's why the voiding diary is basically the in and out of the day, how much in, fluid in, versus how much fluid out.
So frequent drinking in and of itself does not mean anything. If they're drinking three liters of fluid a day and they're not a marathon runner, that means something. But I've had marathon runners drink three liters and it's okay because they're out there running all the time.
So, again, that's where you have to look at the whole, big picture. But on the average, large volume, greater than say two liters a day is above the average. That will lead to frequent urination because the bladder will just fill up.
Q. So if a woman drinks more than one to two liters of fluid a day, that will lead to frequent urination because the

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bladder will just fill up.
A. Well, no. I said -- I said more than two. Average consumption a day is one to 1.5 liters of fluid but that's also not counting food because about a third of your urine can be from breakdown of food. So, again, it gets very complicated.
Q. So if a woman drinks more than two liters a day, there will be more frequent urination because the bladder will fill up?
A. Unless they're exercising a lot and then they'll burn the fluid off or if it's hot or they're in a humid environment. So that's why you have to look at the whole totality.
Q. Urinary urgency, how is that diagnosed?
A. The most accurate way to diagnose urgency is by history, what the patient tells you.
Q. Does a history of -- what are the factors that are involved in urinary urgency?
A. Factors that are involved? I

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guess I don't understand what you mean by factors that are involved.
Q. What are the things that lead to the acute onset of the need to void?
A. Well, that indicates the possibility of a bladder that is malfunctioning, meaning it does spasms, but urgency can also be in the setting of a bladder that does not empty out very well either.
And so bladder sensation is immensely complicated and those patterns can then be learned in the spinal cord, which actually the glial cells or astrocytes in the spinal cord can learn behavior.
Everything we do is learned, whether it be typing on a computer or reading, driving, that's learned, but then also a body can learn bad habits.
Q. Can urinary urgency be a sporadic symptom?
A. If there is something in the bladder that is an irritant, most likely example in that situation would be something like a bladder infection, then you treat the

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bladder infection, the bladder goes back down to its baseline. So urgency of urination can occur in that. If it's a neurologic or idiopathic, it's going to be the same, maybe precipitated by caffeine consumption, stress, nicotine.
Q. Medications?
A. Certain medications, cold medication, anything that is to clear the respiratory tract can cause it.
Q. Did Mrs. Wicker have bladder pain before her Prolift® procedure?
A. I'd have to look back at the records.
Q. Did Mrs. Wicker have urinary frequency before her Prolift® procedure?
A. Again, I'd have to go back and look at the records.
Q. Did Mrs. Wicker have urinary urgency before her Prolift® procedure?
A. I don't recall them ever saying that. I do recall that they said right prior to surgery, no urinary symptoms but she may have had a history of interstitial cystitis.

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Q. You're aware that she did have a history of interstitial cystitis.
A. Yes.
Q. And that was before Prolift®; correct?
A. Correct.
Q. Can interstitial cystitis also lead to urinary frequency?
A. Yes.
Q. Can interstitial cystitis also lead to urinary urgency?
A. No. Urgency is an -- excludes the diagnosis. It is -- that indicates overactive bladder. Interstitial cystitis has pain with filling, not urgency.
Q. And you say that those symptoms she experienced since Prolift® surgery is a result of irritation of the bladder and pelvic neuroanatomy?
A. Correct.
Q. Is that different from what you believe occurred with regard to Mrs. Gross?
A. Well, Mrs. Gross had different symptomatology, different manifestation of the injury, hence, that indicates to me

different pelvic neuroanatomy was involved because, again, you have the sympathetic and parasympathetic nervous system right in that area. They do different things.

And also you have with the trocars of the Prolift® with the potential for pudendal nerve issues, too. And that controls a completely different aspect of urination and sensation.

Q. In your report did you specifically opine that the trocars from the Prolift® caused some type of injury to Mrs. Wicker?

A. Well, no. I say the Prolift® surgery. That's all-encompassing so that could include or it does not exclude trocar use.

Q. Did the trocar use in Mrs. Wicker's surgery cause her any of these symptoms or injuries that you have set forth in your report?

A. I can't say they did or did not. I said they could be a contributing factor but I've not -- I have not opined that they did or did not.

Q. And you comment on the pain of pelvic floor myalgia with Mrs. Wicker; correct?

A. Yes.

Q. You saw that Dr. Weber also opined on that subject?

A. Yes.

Q. You saw that Dr. Margolis also opined on that subject?

A. Yes.

Q. Do you believe that something different should have been done by Mrs. Wicker's physicians to treat her pain?

A. No. I think they're -- they're doing everything they can.

Q. Do you believe that something different should have been done with regard to Mrs. Wicker's pelvic floor myalgia?

A. No. I think they're doing everything they can. And according to Dr. Raz's deposition, which I watched the video on, he would -- he's doing exactly what I would have done.

Q. You saw Dr. Raz performed a prolapse surgery on Mrs. Wicker, then?

A. No. I saw the -- his deposition, his video deposition. I didn't see his surgery.

Q. Didn't he testify about that surgery he performed in Mrs. Wicker for prolapse?

A. Yeah. But you say you saw doctor, it's Raz, R-A-Z, not Rose, you saw Dr. Rose -- Dr. Raz performed a prolapse surgery.

Oh, I see. I thought you said did I actually visualize the surgery. I misunderstood your question.

Yes, I saw that he performed a prolapse surgery. Yes. That's my fault.

Q. And in it Dr. Raz described it as a procedure by which he wove different sutures to form a net.

A. Yeah. He used, as I recall, interlocking Prolene sutures.

Q. To form a net.

A. I wouldn't call it a net. I'd call them interlocking sutures in a row. And I don't recall how many he used to help -- help hold up the bladder.

Q. Are you aware of any randomized, controlled trials looking at that Raz surgery of interlocking sutures --

A. No.

Q. -- to treat prolapse?

A. No.

Q. For Mrs. Wicker, is it possible that her bladder pain will at some point go away?

A. I -- I hope so. I have no idea.

Q. You cannot say for certain whether her bladder pain will go away or not.

A. No. No. These mesh complications are too soon. We don't know long term.

Q. Is it possible that Mrs. Wicker's urinary frequency will go away?

A. It is possible.

Q. Urinary frequency can diminish over time; correct?

A. Depending on the underlying insult or the etiology of it, yes.

Q. Urinary urgency can go away with the passage of time; correct?

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A. Again, that depends upon the etiology. If it's idiopathic, usually no. If there's some insult that can be corrected and there's been no damage to the neuroanatomy, then yes.
Q. How is urinary frequency treated, non-idiopathic urinary frequency?
A. Trying to relieve the underlying insult or etiology. If you're not able to treat the underlying etiology, then you can try medications like -- well, you can do time voiding, meaning the patient goes to the bathroom on a schedule.
You can try avoidance of dietary irritants, big three, caffeine, nicotine and then stress is not a dietary irritant but it's an irritant.
Pelvic floor retraining, bladder retraining. At times, vaginal estrogen replacement. Then if you're into the medication, then it's the anticholinergic medications, which there's a whole host of those.
If that fails, then you have Botox injections to the bladder, which need

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to be repeated on the average every four to six months.
If that fails, interstim, which is -- or peripheral nerve stimulation of some sort.
If that fails and the patient is miserable, bladder augmentation surgery, which is a major step, which is not done very often anymore.
Q. Do you know if Mrs. Wicker was compliant with recommendations for her to use vaginal estrogen?
A. I don't know.
Q. Do you know if Mrs. Gross was compliant with recommendations for her to use vaginal estrogen?
A. I don't know. I don't recall reading that in the -- or hearing it in the deposition.
Q. What type of medications can one take for urinary urgency?
A. It's the same thing as frequency. It's the anticholinergics, which is a large family of medication. I shouldn't say a large family. There's six or seven of them.

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Q. Can you tell me the names of just a couple so I --
A. Oxybutynin, which is the trade name is Ditropan, then there's oxybutynin ER, trade name Ditropan XL, Detrol, Detrol LA, Vesicare, Enablex, Sanctura. Imipramine is an old medication I don't use. That's a good list.
(Recess, 2:39-2:50 p.m.)
BY MR. SNELL:
Q. You make mention of recurrent erosions in Mrs. Wicker's case in your November 7th, 2012, report.
A. Yes.
Q. I assume you mean recurrent exposures.
A. Exposures, yes.
Q. There was no mesh erosion in Mrs. Wicker; correct?
A. I am not familiar within the records of any mesh erosions. It was all exposures.
Q. With regard to Mrs. Wicker's pelvic floor myalgia, is it possible that that will get better over time?

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A. If the underlying irritation, inflammation gets better, there's the possibility of that, yes.
Q. Do you have an opinion as to whether the underlying irritation or inflammation will get better?
A. I don't think we know yet. The mesh complications, as I mentioned, are still evolving. We don't know the long term yet. And I think -- I'm afraid it's going to take us many years to get to that conclusion.
Q. You would agree that if Mrs. Wicker's cystocele can be repaired, her dysfunctional voiding condition will get better; correct?
A. Yeah. If the obstruction due to the cystocele, as Dr. Raz described, if that can be corrected, then usually the voiding dysfunction will improve. However, the bladder can learn or the spinal cord can learn habits, so you don't always have complete resolution of the symptoms.
Q. The obstruction due to the cystocele is actually a mechanical

obstruction; correct?
A. That is correct.
Q. And once that mechanical obstruction is removed from the equation, then the voiding dysfunction can return to -- strike that. Start all over again.
And once that mechanical obstruction is removed from the equation, voiding conditions can normalize; correct?
A. There is -- there is a chance of it, yes.
Q. Prolapse can lead to voiding dysfunction; correct?
A. Yes.
Q. Is it a certain type of prolapse or any prolapse, be it anterior, posterior, apical?
A. It would be specifically related to the bladder. So posterior prolapse and rectum is unlikely to be causing much in the way of voiding dysfunction.
Apical prolapse also is unlikely to. It possibly could but, again, if it doesn't involve the bladder, it should not impede much.

Anterior prolapse can cause urinary urgency, frequency, poor emptying, those things; however, it is relatively rare for a prolapse to cause much in the way of voiding dysfunction.
Q. Cystocele is a prolapse of the bladder?
A. Correct. Specifically, yes, cystocele.
Q. And with a cystocele a woman can have voiding dysfunction; correct?
A. That is correct.
Q. And it's your opinion that the rate of voiding dysfunction with cystocele is rare?
A. The rate of obstruction from a cystocele is rare, causing urinary urgency, frequency, is also somewhat rare but a little bit more common. I don't know specific statistics on that.
Q. Have we covered the case-specific opinions you intend to offer on Mrs. Gross and Mrs. Wicker?
A. I believe so, yes.
MR. ANDERSON: Objection.

Except anything I may ask him.
MR. SNELL: Let's go off the record. Let me just check and see if I have anything else.
MR. ANDERSON: Okay.
(Discussion off the record.)
MR. SNELL: Let's go back on.
BY MR. SNELL:
Q. In Mrs. Wicker's case, when you refer to irritation of the pelvic neuroanatomy --
A. Yes.
Q. -- what are you referring to there?
A. Specifically, pudendal nerve, parasympathetic, sympathetic nervous system.
Q. Is it your opinion that Mrs. Wicker had an injury to her pudendal nerve?
A. No. I'm saying that's within the realm of possibility.
Q. Is it your opinion that Mrs. Wicker had an injury to her parasympathetic nerves?
A. I'm saying that she has symptoms

consistent with injury or irritation or insult to the pudendals and the sympathetic and parasympathetic.
Q. So you have an opinion that her symptoms are consistent with an injury to the pudendal, sympathetic and parasympathetic nerves; correct?
A. Correct.
Q. But you have not formed an opinion as to whether there was an actual injury to her pudendal, sympathetic or parasympathetic nerves; correct?
A. Well, I have an opinion in that she was fine before surgery or minimum symptomatology. Following surgery, she had severe symptomatology. So, yeah, there -- there is injury to those nerves. We know based upon her symptoms because those symptoms are carried in those nerve fibers.
Q. How do you know that she does not have injury to the sympathetic but no injuries to the pudendal and parasympathetic?
A. Sympathetic would be responsible for contraction of the bladder neck and

filling of the bladder neck, filling of the bladder. If you have irritation to those nerves, that's going to impair the filling phase. So subsequently you can get frequency, you can get urgency because these nervous systems, all three, work in concert and they all have to be finely tuned, and if you disrupt one without affecting the other, that will throw everything off.

And so based upon the symptomatology, I can go down the nervous system of what may be responsible for that.

Q. Well, what I want to understand is, do you have an opinion to a reasonable degree of medical certainty that Mrs. Wicker's pudendal nerves were injured, not that they may have been injured but that they actually were injured?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: I cannot say since I was not in the surgery that a trocar or mesh were put through those nerves. I can't say that. All I can go off of is the symptomatology following surgery.

Pudendal nerve irritation can present with urinary frequency, slowed urinary stream due to effects of the external sphincter muscle, and so that can cause those symptoms. What I can say is it's consistent with. I cannot prove.

BY MR. SNELL:

Q. Can pelvic -- can urinary dysfunction be a result of pelvic floor spasms?

A. Well, pelvic floor spasms aren't -- aren't a diagnosis. I think that's along the lines of pelvic floor myalgia. And then yes. Your question was dysfunction, yes.

To answer your question, yes, urinary dysfunction can be a result of pelvic floor myalgia, as I call it, not spasms.

Q. Urinary dysfunction can be a result of pelvic floor myalgia; correct?

A. Yes.

Q. What is the difference, Doctor, between pelvic floor myalgia and pelvic floor spasms?

A. Well, spasms is kind of a

description of -- of literally a muscle spasm. Myalgia is indicating pain or tightening of the pelvic floor. You're technically correct, it's just not the terms that we use in the voiding dysfunction world.

Q. Okay.

MR. SNELL: Can we just go off?

(Discussion off the record.)

MR. SNELL: Back on.

BY MR. SNELL:

Q. You would agree, Doctor, that surgeons obtain information pertinent to surgery from numerous sources; correct?

A. Yes.

Q. Surgeons obtain information relevant to a surgery they may seek to perform from their education; correct?

A. Yes.

Q. Their training; correct?

A. Yes.

Q. They may obtain information relevant to a surgery they will perform from their colleagues.

A. Yes.

Q. They can obtain information relevant to a surgery they may perform by attending conferences such as those you have attended?

A. Yes.

Q. Surgeons can obtain information relevant to a surgery they may perform from the medical literature?

A. Yes.

Q. Do you regularly read the medical literature?

A. Yes.

MR. ANDERSON: Objection.

THE WITNESS: Yes.

BY MR. SNELL:

Q. Are there certain -- strike that.

Are there certain journals that you have regularly read in the medical literature since you graduated from medical school?

A. Yeah. That -- that has changed over time with the access to the Internet. It used to be limited to specifically the ones we'd get paper copies, which would be

Journal of Urology, Urology, and then Journal of Neurourology and Urodynamics, I think, but now with the Internet we have access to PubMed, which actually is better because now we get gynecology and OB. It's easy access.

Q. When did you obtain access to PubMed at the Mayo Clinic?

A. I don't know when it became available. I mean, it would have been 2000-something. I'd have to go back and look for it. I don't know. We always had a Medline search or something like that.

Q. So if you wanted to do research on a medical issue when you were at Mayo Clinic, you could perform that type of literature search?

A. Correct.

Q. Surgeons obtain information relevant to surgery from their actual clinical experience with that surgery as well; correct?

A. That is correct.

Q. And that is a very important source of information with regard to a

surgery; correct?

A. Yes.

Q. The first da Vinci robot surgery you performed was in approximately 2001 or 2002; correct?

A. Correct.

Q. And you performed that with your colleague, Dr. George Chow; correct?

A. Correct.

Q. And he is actually the one who is fellowship trained in robotics; correct?

A. Correct.

Q. He is actually the one who drives the robot; correct?

A. Yes.

Q. Do you feel comfortable driving the robot during a robotic laparoscopic sacrocolpopexy?

A. No.

Q. Do you agree that it takes a high degree of training to perform robotic laparoscopic sacrocolpopexy?

A. It takes experience above and beyond just a normal surgeon.

Q. Are you credentialled to perform

the da Vinci robotic laparoscopic sacrocolpopexy?

A. No.

Q. Does Mayo Clinic have a specific credentialling program for a surgeon who would wish to do the da Vinci robotic laparoscopic sacrocolpopexy?

A. No. As long as you've been able to show proficiency in robotic procedure, you would be able to do it. But you have to be able to show proficiency in robotics and have to -- I mean, you're going to have to be in the urogynecology or urology department to do it. A general surgeon is not going to do it.

Q. If you wanted to perform a robotic laparoscopic sacrocolpopexy, you meaning drive the robot, would Mayo Clinic allow you to do that?

A. After performing a certain number under supervision, yes.

Q. Is the credentialling process at Mayo Clinic for being able to perform a laparoscopic sacrocolpopexy versus a robotic laparoscopic sacrocolpopexy any different?

A. I don't know the answer to that because Dr. Chow is fellowship trained in both so there was never an issue as far as credentialling and nobody at Mayo that I know of does a pure laparoscopic sacrocolpopexy. That's a difficult procedure.

Q. A laparoscopic sacrocolpopexy you would agree is a difficult procedure?

A. Yes.

MR. SNELL: That's all the questions I have for right now.

(Whereupon the deposition concluded at 3:12 p.m.)

TESTIMONY CLOSED

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

It was not requested before completion of the deposition that the witness, DANIEL STEVEN ELLIOTT, M.D., have the opportunity to read and sign the deposition transcript.

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LAWYER'S NOTES

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